IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC, Plaintiffs, v. EXELA PHARMA SCIENCES, LLC, EXELA PHARMSCI, INC., and EXELA HOLDINGS, INC., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC ("Roche") (collectively, "Plaintiffs"), for their Complaint against Defendants Exela Pharma Sciences, LLC, Exela PharmSci, Inc., and Exela Holdings, Inc. (collectively, "Exela" or "Defendants"), 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 Exela Pharma Sciences, LLC ("Exela Pharma"), is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 1325 William White Place NE, Lenoir, North Carolina 28645. Upon information and belief, Defendant Exela Pharma manufactures, markets, and/or

sells various generic drug products for sale and use in the State of Delaware and throughout the United States.

4. Upon information and belief, Defendant Exela Pharma is a wholly-owned subsidiary of Exela PharmSci, Inc. ("Exela PharmSci").

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

6. Upon information and belief, Defendant Exela Holdings, Inc. ("Exela Holdings") is the parent company of Defendant Exela PharmSci.

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

8. 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

9. This is a civil action concerning the infringement of United States Patent No. 8,518,981 ("the '981 patent") and United States Patent No. 8,598,218 ("the '218 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

10. 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.

11. 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.

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

13. This Court has personal jurisdiction over Defendants by virtue of the fact that, *inter alia*, Defendants have 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 Defendants for the additional reasons set forth below, and for other reasons that will be presented to the Court if such jurisdiction is challenged.

14. This Court has personal jurisdiction over Defendant Exela Pharma 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 NDA No. 207963; (3) has purposely availed itself of the privilege of doing business in this Judicial District; (4) maintains extensive systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents; and (5) has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court.

15. This Court has personal jurisdiction over Defendant Exela PharmSci by virtue of the fact that, *inter alia*, it: (1) engages in persistent conduct within Delaware, with and through its subsidiary Exela Pharma, a Delaware Corporation, including, upon information and belief, the preparation and submission of NDA No. 207963; (2) has purposely availed itself of

the privilege of doing business in this Judicial District including through, *inter alia*, Exela Pharma, a Delaware Corporation; (3) has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction; 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 through, *inter alia*, Exela Pharma.

16. This Court has personal jurisdiction over Defendant Exela Holdings by virtue of the fact that, *inter alia*, it: (1) is incorporated in Delaware; (2) engages in persistent conduct within Delaware, with and through its subsidiary Exela Pharma, a Delaware Corporation, including, upon information and belief, the preparation and submission of NDA No. 207963; (3) has purposely availed itself of the privilege of doing business in this Judicial District including through, *inter alia*, Exela Pharma, a Delaware Corporation; (4) has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction; and (5) maintains extensive systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents through, *inter alia*, Exela Pharma.

THE PATENTS-IN-SUIT

17. 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 A.

18. 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 B.

19. Pursuant to 21 U.S.C. § 355(b)(1), the '981 patent and the '218 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 '981 PATENT BY EXELA'S 505(b)(2) APPLICATION

20. Plaintiffs reallege paragraphs 1-19 as if fully set forth herein.

21. Upon information and belief, Defendants 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 '981 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 '981 patent.

22. 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 '981 patent are invalid and/or not infringed by NDA No. 207963. Defendants notified Plaintiffs of their certification and provided a detailed statement of the alleged basis for the certification.

23. Defendants' submission to the FDA of NDA No. 207963, including the § 505(b)(2)(A)(iv) allegations, constitutes infringement of the '981 patent under 35 U.S.C. § 271(e)(2)(A).

24. Exela Pharma, Exela PharmSci, and Exela Holdings are jointly and severally liable for any infringement of the '981 patent. This is because, upon information and

belief, Exela Pharma, Exela PharmSci, and Exela Holdings actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of NDA No. 207963 to the FDA.

25. Defendants' 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(j)(2)(A)(vii)(IV) certification constitutes infringement of the '981 patent under 35 U.S.C. § 271(e)(2)(A).

26. Plaintiffs are entitled to a declaration that, if Defendants commercially manufacture, use, offer for sale, or sell their proposed generic versions of Helsinn's Aloxi® brand products within the United States, import their proposed generic versions of Helsinn's Aloxi® brand products into the United States, and/or induce or contribute to such conduct, Defendants will infringe the '981 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

COUNT II – INFRINGEMENT OF THE '218 PATENT BY EXELA'S 505(b)(2) APPLICATION

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

29. Upon information and belief, Defendants 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 '218 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 '218 patent.

30. 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 '218 patent are invalid and/or not infringed by NDA No. 207963. Defendants notified Plaintiffs of their certification and provided a detailed statement of the alleged basis for the certification.

31. Defendants' submission to the FDA of NDA No. 207963, including the § 505(b)(2)(A)(iv) allegations, constitutes infringement of the '218 patent under 35 U.S.C. § 271(e)(2)(A).

32. Exela Pharma, Exela PharmSci, and Exela Holdings are jointly and severally liable for any infringement of the '218 patent. This is because, upon information and belief, Exela Pharma, Exela PharmSci, and Exela Holdings actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of NDA No. 207963 to the FDA.

33. Defendants' 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(j)(2)(A)(vii)(IV) certification constitutes infringement of the '218 patent under 35 U.S.C. § 271(e)(2)(A).

34. Plaintiffs are entitled to a declaration that, if Defendants commercially manufacture, use, offer for sale, or sell their proposed generic versions of Helsinn's Aloxi® brand products within the United States, import their proposed generic versions of Helsinn's Aloxi® brand products into the United States, and/or induce or contribute to such conduct, Defendants will infringe the '218 patent under 35 U.S.C. § 271(a), (b), and/or (c).

35. Plaintiffs will be irreparably harmed by Defendants' 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 have infringed the '981 and '218 patents by submitting NDA No. 207963;

B. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of NDA No. 207963 be a date that is not earlier than the expiration dates of the '981 and '218 patents, or any later expiration of exclusivity for either of these patents to which Plaintiffs are or become entitled;

C. An Order be issued that Defendants, 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, 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 '981 and '218 patents, prior to the expiration 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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