IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HELSINN HEALTHCARE S.A., HELSINN ADVANCED SYNTHESIS S.A., HELSINN BIREX PHARMACEUTICALS LTD. and HELSINN THERAPEUTICS (U.S.), INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
BAXTER HEALTHCARE CORPORATION,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Helsinn Healthcare S.A. ("Helsinn S.A."), Helsinn Advanced Synthesis S.A. ("Helsinn Advanced"), Helsinn Birex Pharmaceuticals Ltd. ("Helsinn Birex"), and Helsinn Therapeutics (U.S.), Inc. ("Helsinn U.S.") (collectively, "Plaintiffs"), for their Complaint against Defendant Baxter Healthcare Corporation ("Baxter" or "Defendant"), hereby allege as follows:

THE PARTIES

1. Plaintiff Helsinn S.A. is a Swiss corporation having its principal place of business at Via Pian Scairolo, 9, CH-6912 Lugano-Pazzallo, Switzerland.

2. Plaintiff Helsinn Advanced is a Swiss corporation having its principal place of business at Via Industria, 24, CH-6710, Biasca, Switzerland.

3. Plaintiff Helsinn Birex is an Irish corporation having its principal place of business at Damastown, Mulhuddart, Dublin 15.

4. Plaintiff Helsinn U.S. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 170 Wood Avenue South, 5th Floor, Iselin, New Jersey, 08830.

5. Upon information and belief, Defendant Baxter is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015. Upon information and belief, Baxter manufactures, markets, and/or sells various generic pharmaceutical drugs for use throughout the United States, including in the State of Delaware.

NATURE OF THE ACTION

6. This is a civil action concerning the infringement of United States Patent No. 8,598,219 ("the '219 patent") and United States Patent No. 8,729,094 ("the '094 patent") (collectively, "the patents-in-suit"). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

JURISDICTION AND VENUE

7. 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.

8. 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.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1400(b).

10. This Court has personal jurisdiction over Defendant Baxter by virtue of the fact that, *inter alia*, it: (1) is incorporated in Delaware; (2) has purposely availed itself of the privilege of doing business in this Judicial District; (3) maintains systematic contacts with the State of Delaware, including marketing, distribution, and/or sale of pharmaceutical drugs to Delaware residents; and/or (4) has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court.

THE PATENTS-IN-SUIT

11. On December 3, 2013, the '219 patent, titled, "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Helsinn S.A. as an assignee, and as of May 1, 2017, co-ownership rights thereto have been granted to each of Helsinn Advanced, Helsinn Birex, and Helsinn U.S. A copy of the '219 patent is attached as Exhibit A.

12. On May 20, 2014, the '094 patent, titled, "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Helsinn S.A. as an assignee, and as of May 1, 2017, co-ownership rights thereto have been granted to each of Helsinn Advanced, Helsinn Birex, and Helsinn U.S. A copy of the '094 patent is attached as Exhibit B.

13. Pursuant to 21 U.S.C. § 355(b)(1), 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

14. Plaintiffs hold New Drug Application ("NDA") No. 021372 for an injectable solution containing 0.25 mg / 5 mL of the active pharmaceutical ingredient palonosetron hydrochloride. Plaintiffs market and sell this product in the United States under the brand name "Aloxi®."

15. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the FDA publication titled, "Approved Drug Products with Therapeutic Equivalence Evaluations" (also known as the "Orange Book") as covering Aloxi® or its use.

16. Plaintiffs received written notification of Baxter's ANDA No. 206916 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by letter dated September 12, 2018 ("Notice Letter").

17. This action was commenced within 45 days of Plaintiffs receiving the Notice Letter.

COUNT I – INFRINGEMENT OF THE '219 PATENT

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

19. Upon information and belief, Defendant Baxter submitted ANDA No. 206916 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 206916 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic 0.25 mg / 5 mL palonosetron hydrochloride intravenous solution prior to the expiration of the '219 patent. Upon information and belief, ANDA No. 206916 seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.25 mg / 5 mL palonosetron hydrochloride intravenous solution prior to the expiration of the '219 patent.

20. Upon information and belief, ANDA No. 206916 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, unenforceable, and/or not infringed.

21. Defendant Baxter's submission to the FDA of ANDA No. 206916, including the § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

22. In its September 12, 2018 Notice Letter, Baxter did not assert any grounds for noninfringement of the claims of the '219 patent other than their alleged invalidity.

23. Plaintiffs are entitled to a declaration that, if Defendant Baxter commercially manufactures, uses, offers for sale, or sells its proposed generic version of Helsinn's Aloxi® brand products within the United States, imports its proposed generic version

of Helsinn's Aloxi® brand products into the United States, and/or induces or contributes to such conduct, Defendant Baxter will infringe the '219 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

25. On May 1, 2017, the U.S. Court of Appeals for the Federal Circuit ("the Federal Circuit") held that certain claims of the '219 patent are invalid. *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1360 (Fed. Cir. 2017). Plaintiffs have appealed that decision to the U.S. Supreme Court ("the Supreme Court"), and the Supreme Court has granted Plaintiffs' petition for certiorari. *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 138 S. Ct. 2678 (2018). If the Supreme Court affirms the Federal Circuit's decision of invalidity of the '219 patent, Plaintiffs will dismiss Count I from this action.

COUNT II – INFRINGEMENT OF THE '094 PATENT

26. Plaintiffs reallege paragraphs 1-25 as if fully set forth herein.

27. Upon information and belief, Defendant Baxter submitted ANDA No. 206916 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 206916 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic 0.25 mg / 5 mL palonosetron hydrochloride intravenous solution prior to the expiration of the '094 patent. Upon information and belief, ANDA No. 206916 seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.25 mg / 5 mL palonosetron hydrochloride intravenous solution prior to the expiration of the '094 patent.

28. Upon information and belief, ANDA No. 206916 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, unenforceable, and/or not infringed.

29. Defendant Baxter's submission to the FDA of ANDA No. 206916, including the § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

30. Plaintiffs are entitled to a declaration that, if Defendant Baxter commercially manufactures, uses, offers for sale, or sells its proposed generic version 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 Baxter will infringe the '094 patent under 35 U.S.C. § 271(a), (b), and/or (c).

31. Plaintiffs will be irreparably harmed by Defendant Baxter'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 Baxter has infringed the '219 and '094 patents by submitting ANDA No. 206916 to the FDA;

B. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 206916 be a date that is not earlier than the expiration dates of the '219 and '094 patents, or any later expiration of exclusivity for either of those patents to which Plaintiffs are or become entitled.

C. An Order be issued that Defendant Baxter, its officers, agents, servants and employees, and those persons in active concert or participation with it, are preliminarily and

permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing the proposed generic version of Helsinn's Aloxi® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '219 and '094 patents, prior to the expiration of either 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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October 25, 2018