IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACCORD HEALTHCARE, INC. and INTAS PHARMACEUTICALS LTD.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC ("Roche") (collectively, "Plaintiffs"), for their Complaint against Defendants Accord Healthcare, Inc. ("Accord") and Intas Pharmaceuticals Ltd. ("Intas") (collectively, "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 Accord is a corporation organized and existing under the laws of the State of North Carolina with its principal place of business at 1009 Slater Road, Suite 210B, Durham, North Carolina 27703.

4. Upon information and belief, Defendant Intas is a corporation organized under the laws of India, with its principal place of business at Chinubhai Center, Off. Nehru Bridge, Ashram Road, Ahmedabad, Gujarat 380009, India.

5. Upon information and belief, Defendant Accord is a wholly owned subsidiary and agent of Intas.

6. Upon information and belief, Intas manufactures, markets, and/or sells through Accord various generic drug products for sale and use throughout the United States, including in the State of Delaware.

7. Upon information and belief, the acts of Accord complained of herein were done at the direction of, with the authorization of, and with the cooperation, assistance, and/or participation of Intas.

NATURE OF THE ACTION

8. This is a civil action concerning the infringement of United States Patent No. 8,598,218 ("the '218 patent") and United States Patent No. 8,598,219 ("the '219 patent"). 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

9. 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.

10. 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.

11. 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).

12. This Court has personal jurisdiction over Defendants by virtue of the fact that, *inter alia*, both 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.

13. This Court has personal jurisdiction over Accord by virtue of the fact that, *inter alia*, it: (1) has purposely availed itself of the privilege of doing business in this Judicial District; (2) maintains systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents; and (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.

14. This Court has personal jurisdiction over Intas by virtue of the fact that, *inter alia*, it: (1) has purposely availed itself of the privilege of doing business in this Judicial District through, *inter alia*, Accord; (2) maintains systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents through, *inter alia*, Accord; and (3) has agreed not to contest and to abide by a judgment or order issued by this Court in a currently pending patent infringement action, and to be subject to discovery in that action, including the production of documents and deposition of its employees, both in their personal capacity and on behalf of Intas.

THE PATENTS-IN-SUIT

15. 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 A.

16. 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 B.

17. Pursuant to 21 U.S.C. § 355(b)(1), the '218 and '219 patents have been 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 '218 PATENT

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

19. Upon information and belief, Defendants submitted ANDA No. 204615 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 204615 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. ANDA No. 204615 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.

20. The '218 patent had not issued at the time Defendants made their § 505(j)(2)(A)(vii)(IV) certification regarding certain of Plaintiffs' other Orange Book-listed patents.

21. Upon information and belief, Defendants are required by law to either amend their ANDA to contain a § 505(j)(2)(A)(vii)(IV) certification with respect to the '218 patent, or must relinquish their request that the FDA approve ANDA No. 204615 prior to the expiration of that patent.

22. Defendants continue to seek approval of ANDA No. 204615 from the FDA and intend to continue 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 the ’218 patent.

23. By seeking approval of their ANDA 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 the ’218 patent, Defendants have infringed that patent pursuant to 35 U.S.C. § 271(e)(2)(A).

24. Accord and Intas are jointly and severally liable for any infringement of the ’218 patent. This is because, upon information and belief, Accord and Intas actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 204615 to the FDA.

25. Defendants’ active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 204615 constitutes infringement of the ’218 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 ’218 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 ’219 PATENT

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

29. Upon information and belief, Defendants submitted ANDA No. 204615 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 204615 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 '219 patent. ANDA No. 204615 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 '219 patent.

30. The '219 patent had not issued at the time Defendants made their § 505(j)(2)(A)(vii)(IV) certification regarding certain of Plaintiffs' other Orange Book-listed patents.

31. Upon information and belief, Defendants are required by law to either amend their ANDA to contain a § 505(j)(2)(A)(vii)(IV) certification with respect to the '219 patent, or must relinquish their request that the FDA approve ANDA No. 204615 prior to the expiration of that patent.

32. Defendants continue to seek approval of ANDA No. 204615 from the FDA and intend to continue 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 the '219 patent.

33. By seeking approval of their ANDA 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 the '219 patent, Defendants have infringed that patent pursuant to 35 U.S.C. § 271(e)(2)(A).

34. Accord and Intas are jointly and severally liable for any infringement of the '219 patent. This is because, upon information and belief, Accord and Intas actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 204615 to the FDA.

35. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 204615 constitutes infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

36. 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 '219 patent under 35 U.S.C. § 271(a), (b), and/or (c).

37. 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 '218 and '219 patents by submitting ANDA No. 204615;

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. 204615 be a date that is not earlier than the expiration dates of the '218 and '219 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 '218 or '219 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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