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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A.,

Plaintiff,

v.

ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED (d/b/a ZYDUS CADILA),

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiff Helsinn Healthcare S.A. ("Helsinn") for its Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Cadila Healthcare Ltd. d/b/a Zydus Cadila ("Zydus Cadila") (collectively, "Defendants") hereby alleges 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. Upon information and belief, Zydus USA is an entity organized and existing under the laws of the State of New Jersey, with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Upon information and belief, Defendant Zydus USA manufactures, markets, and/or sells various generic drug products for sale and use in the State of New Jersey and throughout the United States.

3. Upon information and belief, Zydus Cadila is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad, 380015 Gujarat, India. On information and belief, Defendant Zydus Cadila, itself and/or through its subsidiary, agent and alter ego, Zydus USA, manufactures, markets, and/or sells various generic drug products for sale and use in the State of New Jersey and throughout the United States.

NATURE OF THE ACTION

4. This is a civil action concerning the infringement of United States Patent No. 7,947,724 ("the '724 patent"), United States Patent No. 7,947,725 ("the '725 patent"), United States Patent No. 7,960,424 ("the '424 patent"), United States Patent No. 8,598,219 ("the '219 patent"), and United States Patent No. 8,729,094 ("the '094 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

5. 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.

6. 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.

7. Venue is proper in this Court as to Zydus USA and Zydus Cadila pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

8. 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 an act of patent infringement that has led to foreseeable harm and injury to Helsinn. 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.

9. This Court has personal jurisdiction over Zydus USA because, *inter alia*, it: (1) is incorporated in New Jersey; (2) has its principal place of business in New Jersey; (3) has purposely availed itself of the privilege of doing business in this Judicial District; (4) maintains extensive systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to New Jersey residents; and (5) has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court.

10. This Court has personal jurisdiction over Zydus Cadila because, *inter alia*, it: (1) has purposely availed itself of the privilege of doing business in New Jersey including, *inter alia*, through its subsidiary, agent and alter ego, Zydus USA, a company incorporated in

New Jersey, with its principal place of business in New Jersey; (2) maintains extensive systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to New Jersey residents including through, *inter alia*, Zydus USA; and (3) 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 May 24, 2011, the '724 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Helsinn as assignee. A copy of the '724 patent is attached as Exhibit A.

12. On May 24, 2011, the '725 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Helsinn as assignee. A copy of the '725 patent is attached as Exhibit B.

13. On June 14, 2011, the '424 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Helsinn as assignee. A copy of the '424 patent is attached as Exhibit C.

14. On December 3, 2013, the '219 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Helsinn as assignee. A copy of the '219 patent is attached as Exhibit D.

15. On May 20, 2014, the '094 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Helsinn as assignee. A copy of the '094 patent is attached as Exhibit E.

16. Pursuant to 21 U.S.C. § 355(b)(1), the '724 patent, the '725 patent, the '424 patent, 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

COUNT I – INFRINGEMENT OF THE '724 PATENT

17. Helsinn realleges paragraphs 1-16 as if fully set forth herein.

18. Upon information and belief, Zydus USA submitted ANDA No. 209002 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 209002 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic 0.05 mg / mL, 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of certain of Helsinn's Orange Book-listed patents that have the same expiration date as the '724 patent. ANDA No. 209002 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.05 mg / mL, 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '724 patent.

19. Upon information and belief, ANDA No. 209002 includes a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '724 patent are invalid. Zydus USA notified Helsinn of its certification and provided a detailed statement of the alleged basis for the certification, but did not allege noninfringement of any claim of the '724 patent, separate and apart from its assertions that those claims are allegedly invalid.

20. Zydus USA's submission to the FDA of ANDA No. 209002, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

21. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

22. Defendants Zydus USA and Zydus Cadila are jointly and severally liable for any infringement of the '724 patent because Defendants actively and knowingly participated in, contributed to, aided, abetted, and/or induced the submission to the FDA of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) certification of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) allegations.

23. Helsinn is 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 '724 patent under 35 U.S.C. § 271(a), (b), and/or (c).

24. Helsinn will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

COUNT II – INFRINGEMENT OF THE '725 PATENT

25. Helsinn realleges paragraphs 1-24 as if fully set forth herein.

26. Upon information and belief, Zydus USA submitted ANDA No. 209002 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 209002 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic 0.05 mg / mL, 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of certain of Helsinn's Orange Book-

listed patents that have the same expiration date as the '725 patent. ANDA No. 209002 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.05 mg / mL, 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '725 patent.

27. Upon information and belief, ANDA No. 209002 includes a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '725 patent are invalid. Zydus USA notified Helsinn of its certification and provided a detailed statement of the alleged basis for the certification, but did not allege noninfringement of any claim of the '725 patent, separate and apart from its assertions that those claims are allegedly invalid.

28. Zydus USA's submission to the FDA of ANDA No. 209002, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

29. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

30. Defendants Zydus USA and Zydus Cadila are jointly and severally liable for any infringement of the '725 patent because Defendants actively and knowingly participated in, contributed to, aided, abetted, and/or induced the submission to the FDA of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) certification of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) allegations.

31. Helsinn is 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 '725 patent under 35 U.S.C. § 271(a), (b), and/or (c).

32. Helsinn will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

COUNT III – INFRINGEMENT OF THE '424 PATENT

33. Helsinn realleges paragraphs 1-32 as if fully set forth herein.

34. Upon information and belief, Zydus USA submitted ANDA No. 209002 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 209002 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic 0.05 mg / mL, 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of certain of Helsinn's Orange Book-listed patents that have the same expiration date as the '424 patent. ANDA No. 209002 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.05 mg / mL, 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '424 patent.

35. Upon information and belief, ANDA No. 209002 includes a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '424 patent are invalid. Zydus USA notified Helsinn of its certification and provided a detailed statement of the alleged basis for the certification, but did not allege noninfringement of any

claim of the '424 patent, separate and apart from its assertions that those claims are allegedly invalid.

36. Zydus USA's submission to the FDA of ANDA No. 209002, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '424 patent under 35 U.S.C. § 271(e)(2)(A).

37. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '424 patent under 35 U.S.C. § 271(e)(2)(A).

38. Defendants Zydus USA and Zydus Cadila are jointly and severally liable for any infringement of the '424 patent because Defendants actively and knowingly participated in, contributed to, aided, abetted, and/or induced the submission to the FDA of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) certification of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) allegations.

39. Helsinn is 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 '424 patent under 35 U.S.C. § 271(a), (b), and/or (c).

40. Helsinn will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

COUNT IV – INFRINGEMENT OF THE '219 PATENT

41. Helsinn realleges paragraphs 1-40 as if fully set forth herein.

42. Upon information and belief, Zydus USA submitted ANDA No. 209002 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 209002 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic 0.05 mg / mL, 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of certain of Helsinn's Orange Book-listed patents that have the same expiration date as the '219 patent. ANDA No. 209002 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.05 mg / mL, 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '219 patent.

43. Upon information and belief, ANDA No. 209002 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. Zydus USA notified Helsinn of its certification and provided a detailed statement of the alleged basis for the certification but did not allege noninfringement of any claim of the '219 patent, separate and apart from its assertions that those claims are allegedly invalid.

44. Zydus USA's submission to the FDA of ANDA No. 209002, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

45. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

46. Defendants Zydus USA and Zydus Cadila are jointly and severally liable for any infringement of the '219 patent because Defendants actively and knowingly participated in, contributed to, aided, abetted, and/or induced the submission to the FDA of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) certification of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) allegations.

47. Helsinn is 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).

48. Helsinn will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

COUNT V – INFRINGEMENT OF THE '094 PATENT

49. Helsinn realleges paragraphs 1-48 as if fully set forth herein.

50. Upon information and belief, Zydus USA submitted ANDA No. 209002 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 209002 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic 0.05 mg / mL, 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of certain of Helsinn's Orange Book-listed patents that have the same expiration date as the '094 patent. ANDA No. 209002 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.05 mg / mL, 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '094 patent.

51. Upon information and belief, ANDA No. 209002 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. Zydus USA notified Helsinn of its certification and provided a detailed statement of the alleged basis for the certification, but did not allege noninfringement of any claim of the '094 patent, separate and apart from its assertions that those claims are allegedly invalid.

52. Zydus USA's submission to the FDA of ANDA No. 209002, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

53. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

54. Zydus USA and Zydus Cadila are jointly and severally liable for any infringement of the '094 patent because Defendants actively and knowingly participated in, contributed to, aided, abetted, and/or induced the submission to the FDA of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) certification of ANDA No. 209002 and the § 505(j)(2)(A)(vii)(IV) allegations.

55. Helsinn is 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 '094 patent under 35 U.S.C. § 271(a), (b), and/or (c).

56. Helsinn will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Helsinn requests that:

A. A Judgment be entered declaring that Defendants have infringed the '724, '725, '424, '219, and '094 patents by submitting ANDA No. 209002;

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. 209002 be a date that is not earlier than the expiration dates of the '724, '725, '424, '219, and '094 patents, or any later expiration of exclusivity for any of those patents to which Helsinn is or becomes entitled;

C. An Order be issued that Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing 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 '724, '725, '424, '219, and '094 patents, prior to the expiration of any of those patents, including any extensions to which Helsinn is or becomes entitled;

D. Helsinn be awarded attorneys' fees pursuant to 35 U.S.C. § 285;

E. Helsinn be awarded its costs and expenses in this action; and

F. Helsinn be awarded such other and further relief as this Court deems just and proper.

Dated: July 12, 2016

Respectfully submitted,

By: s/ Charles M. Lizza

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Attorneys for Plaintiff
Helsinn Healthcare S.A.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matters captioned *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.,* Civil Action No. 11-3962 (MLC)(DEA) (Consolidated), *Helsinn Healthcare S.A. v. Dr. Reddy's Laboratories, Ltd., et al.,* Civil Action No. 12-2867 (MLC)(DEA) (Consolidated), *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.,* Civil Action No. 14-4274 (MLC)(DEA), *Helsinn Healthcare S.A., et al. v. Hospira, Inc.,* Civil Action No. 15-2077 (Consolidated) (MLC)(DEA), *Helsinn Healthcare S.A., et al. v. Qilu Pharmaceutical Co., Ltd.,* Civil Action No. 15-8132 (MLC)(DEA), *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.,* Civil Action No. 15-8662 (MLC)(DEA), *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., et al.,* Civil Action No. 15-8663 (MLC)(DEA), *Helsinn Healthcare S.A. v. Sagent Pharmaceuticals, Inc.,* Civil Action No. 16-173 (MLC)(DEA), *Helsinn Healthcare S.A. v. Sagent Pharmaceuticals, Inc.,* Civil Action No. 16-681 (MLC)(DEA), and *Helsinn Healthcare S.A., et al. v. Actavis LLC,* Civil Action No. 16-1683 (MLC)(DEA) are related to the matter in controversy because the matter in controversy involves the same plaintiff and the same patents, and because Defendant Zydus is seeking FDA approval to market a generic version of the same pharmaceutical product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: July 12, 2016

Respectfully submitted,

By: s/ Charles M. Lizza

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