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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., SANDOZ INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiffs Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC ("Roche"), for its Complaint against Defendants Dr. Reddy's Laboratories Ltd. ("Reddy Ltd."), Dr. Reddy's Laboratories Inc. ("Reddy Inc."), Sandoz Inc. ("Sandoz"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), hereby allege as follows:

THE PARTIES

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

2. Plaintiff 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 Reddy Ltd. is an Indian corporation having a place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad - 500034, Andhra Pradesh, India. Upon information and belief, Reddy Ltd., itself and through its wholly owned subsidiary and agent Defendant Reddy Inc. (referred to collectively as "Reddy"), manufactures generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Reddy Ltd. has appointed Lee Banks, Esq. of Reddy Inc., 200 Somerset Corporate Boulevard, Floor 7, Bridgewater, New Jersey 08807, as its agent in New Jersey authorized to accept service of process in this action. Reddy Ltd. has previously consented to personal jurisdiction in this Court.

4. Upon information and belief, Defendant Reddy Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 200 Somerset Corporate Boulevard, Floor 7, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary and agent of Defendant Reddy Ltd. Upon information and belief, Reddy Inc.

is registered to do business in New Jersey and does business in this judicial district. Upon information and belief, Reddy Inc. has appointed Lee Banks, Esq. of Reddy Inc., 200 Somerset Corporate Boulevard, Floor 7, Bridgewater, New Jersey 08807, as its agent in New Jersey authorized to accept service of process in this action. Reddy Inc. has previously consented to personal jurisdiction in this Court.

5. Upon information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Colorado, having a place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. Upon information and belief, Sandoz is registered to do business in New Jersey and does business in this judicial district. Upon information and belief, Sandoz has appointed Stephen R. Auten, Esq. of Sandoz, 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540, as its agent in New Jersey authorized to accept service of process in this action. Sandoz has previously consented to personal jurisdiction in this Court.

6. Upon information and belief, Defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677. Teva USA is a wholly owned subsidiary and agent of Defendant Teva Ltd. (referred to collectively as "Teva"). Upon information and belief, Teva USA has facilities in New Jersey, is registered to do business in New Jersey, and does business in this judicial district. Teva USA has previously consented to personal jurisdiction in this Court.

7. Upon information and belief, Defendant Teva Ltd. is an Israeli corporation having a place of business at 5 Basel Street, Petah Tikva 49131, Israel. Upon information and belief, Teva Ltd., itself and through its wholly owned subsidiary and agent Defendant Teva USA,

manufactures generic drugs for sale and use throughout the United States, including in this judicial district. Teva Ltd. has previously consented to personal jurisdiction in this Court.

NATURE OF THE ACTION

8. This is a civil action concerning the infringement of United States Patent No. 7,947,724 ("the '724 patent") and United States Patent No. 7,947,725 ("the '725 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).

10. 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).

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

12. This Court has personal jurisdiction over Defendant Reddy Ltd.

13. This Court has personal jurisdiction over Defendant Reddy Inc.

14. This Court has personal jurisdiction over Defendant Sandoz.

15. This Court has personal jurisdiction over Defendant Teva USA.

16. This Court has personal jurisdiction over Defendant Teva Ltd.

THE PATENTS

17. On May 24, 2011, the '724 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Helsinn and Roche as assignees. A copy of the '724 patent is attached as Exhibit A.

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

ACTS GIVING RISE TO THIS ACTION

COUNT I – INFRINGEMENT OF THE '724 PATENT BY REDDY

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

20. Upon information and belief, Defendant Reddy submitted ANDA No. 201533 to the United States Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 201533 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 and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '724 patent. ANDA No. 201533 specifically seeks FDA approval to market generic versions of Helsinn's Aloxi® brand 0.25 mg / 5 mL and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '724 patent.

21. ANDA No. 201533 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '724 patent are invalid.

22. Reddy's submission to the FDA of ANDA No. 201533, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

23. Reddy Ltd. and Reddy Inc. are jointly and severally liable for any infringement of the '724 patent. This is because, upon information and belief, Reddy Ltd. and Reddy Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of the ANDA No. 201533 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

24. Reddy's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 201533 and the § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

25. Plaintiffs are entitled to a declaration that, if Reddy commercially manufactures, uses, offers for sale, 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, Reddy would infringe the '724 patent under 35 U.S.C. § 271(a), (b), and/or (c).

26. Plaintiffs will be irreparably harmed by Reddy'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 '724 PATENT BY SANDOZ

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

28. Upon information and belief, Defendant Sandoz submitted ANDA No. 202521 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 202521 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 and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of

the '724 patent. ANDA No. 202521 specifically seeks FDA approval to market generic versions of Helsinn's Aloxi® brand 0.25 mg / 5 mL and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '724 patent.

29. ANDA No. 202521 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '724 patent are invalid.

30. Sandoz's submission to the FDA of ANDA No. 202521, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

31. Plaintiffs are entitled to a declaration that, if Sandoz commercially manufactures, uses, offers for sale, 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, Sandoz would infringe the '724 patent under 35 U.S.C. § 271(a), (b), and/or (c).

32. Plaintiffs will be irreparably harmed by Sandoz'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 '724 PATENT BY TEVA

33. Plaintiffs reallege paragraphs 1-32 as if fully set forth herein.

34. Upon information and belief, Defendant Teva submitted ANDA No. 090713 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 090713 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 and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '724 patent. ANDA No. 090713 specifically seeks FDA approval to market generic versions

of Helsinn's Aloxi® brand 0.25 mg / 5 mL and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '724 patent.

35. ANDA No. 090713 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '724 patent are invalid.

36. Teva's submission to the FDA of ANDA No. 090713, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

37. Teva Ltd. and Teva Inc. are jointly and severally liable for any infringement of the '724 patent. This is because, upon information and belief, Teva Ltd. and Teva Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of the ANDA No. 090713 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

38. Teva's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 090713 and the § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

39. Plaintiffs are entitled to a declaration that, if Teva commercially manufactures, uses, offers for sale, 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, Teva would infringe the '724 patent under 35 U.S.C. § 271(a), (b), and/or (c).

40. Plaintiffs will be irreparably harmed by Teva'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 '725 PATENT BY REDDY

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

42. Upon information and belief, Defendant Reddy submitted ANDA No. 201533 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 201533 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 and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '725 patent. ANDA No. 201533 specifically seeks FDA approval to market generic versions of Helsinn's Aloxi® brand 0.25 mg / 5 mL and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '725 patent.

43. ANDA No. 201533 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '725 patent are invalid.

44. Reddy's submission to the FDA of ANDA No. 201533, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

45. Reddy Ltd. and Reddy Inc. are jointly and severally liable for any infringement of the '725 patent. This is because, upon information and belief, Reddy Ltd. and Reddy Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of the ANDA No. 201533 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

46. Reddy's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 201533 and the § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

47. Plaintiffs are entitled to a declaration that, if Reddy commercially manufactures, uses, offers for sale, 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, Reddy would infringe the '725 patent under 35 U.S.C. § 271(a), (b), and/or (c).

48. Plaintiffs will be irreparably harmed by Reddy'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 '725 PATENT BY SANDOZ

49. Plaintiffs reallege paragraphs 1-48 as if fully set forth herein.

50. Upon information and belief, Defendant Sandoz submitted ANDA No. 202521 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 202521 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 and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '725 patent. ANDA No. 202521 specifically seeks FDA approval to market generic versions of Helsinn's Aloxi® brand 0.25 mg / 5 mL and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '725 patent.

51. ANDA No. 202521 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '725 patent are invalid.

52. Sandoz's submission to the FDA of ANDA No. 202521, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

53. Plaintiffs are entitled to a declaration that, if Sandoz commercially manufactures, uses, offers for sale, 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, Sandoz would infringe the '725 patent under 35 U.S.C. § 271(a), (b), and/or (c).

54. Plaintiffs will be irreparably harmed by Sandoz'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 '725 PATENT BY TEVA

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

56. Upon information and belief, Defendant Teva submitted ANDA No. 090713 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 090713 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 and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '725 patent. ANDA No. 090713 specifically seeks FDA approval to market generic versions of Helsinn's Aloxi® brand 0.25 mg / 5 mL and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '725 patent.

57. ANDA No. 090713 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '725 patent are invalid.

58. Teva's submission to the FDA of ANDA No. 090713, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

59. Teva Ltd. and Teva Inc. are jointly and severally liable for any infringement of the '725 patent. This is because, upon information and belief, Teva Ltd. and Teva Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of the ANDA No. 090713 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

60. Teva's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 090713 and the § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

61. Plaintiffs are entitled to a declaration that, if Teva commercially manufactures, uses, offers for sale, 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, Teva would infringe the '725 patent under 35 U.S.C. § 271(a), (b), and/or (c).

62. Plaintiffs will be irreparably harmed by Teva'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 Defendants Reddy Ltd., Reddy Inc., Sandoz, Teva USA, and Teva Ltd. have infringed the '724 and '725 patents by submitting the aforesaid ANDAs;

B. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of any of Defendants' ANDAs identified in this Complaint be a date that is

not earlier than the expiration dates of the '724 patent and '725 patent, or any later expiration of exclusivity for the '724 patent or '725 patent to which Plaintiffs are or become entitled;

C. An Order be issued that Defendants Reddy Ltd., Reddy Inc., Sandoz, Teva USA, and Teva Ltd., 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, 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 '724 or '725 patents, prior to the expiration of the '724 or '725 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.

Dated: July 8, 2011

Respectfully submitted,

By: s/ Charles M. Lizza

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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 above-captioned action is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: July 8, 2011

Respectfully submitted,

By: s/ Charles M. Lizza

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