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. 13-1612 (GMS)
BEN VENUE LABORATORIES, INC. d/b/a BEDFORD LABORATORIES	)	
Defendant.	)	

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC ("Roche") (collectively, "Plaintiffs"), for their Complaint against Defendant Ben Venue Laboratories, Inc. ("Ben Venue") d/b/a Bedford Laboratories ("Bedford") ("Defendant"), 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, Bedford is an unincorporated division of Ben Venue, a corporation organized and existing under the laws of the State of Delaware, both having a place of business at 300 Northfield Road, Bedford, Ohio 44146. Upon information and belief, Ben Venue, directly and/or through Bedford, markets, manufactures, distributes, and sells generic drugs for use in the State of Delaware 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. 8,518,981 ("the '981 patent"), 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.*, as well as the Declaratory Judgments 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 Judgments 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 Defendant pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d) and 1400(b).

8. This Court has personal jurisdiction over Defendant by virtue of the fact that, *inter alia*, 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 Defendant 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.

9. This Court has personal jurisdiction over Defendant by virtue of the fact that, *inter alia*: (1) Ben Venue is incorporated in Delaware; (2) Defendant does

substantial business, derives substantial revenue, and engages in persistent conduct within Delaware, including, upon information and belief, the preparation and submission of ANDA No. 205048; (3) Defendant has purposely availed itself of the privilege of doing business in this Judicial District; (4) Defendant maintains systematic contacts with the State of Delaware, including the sale of generic pharmaceutical drugs to Delaware residents; and (5) Defendant has consented to personal jurisdiction for purposes of this action.

THE PATENTS-IN-SUIT

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

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

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

13. 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 D.

14. 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 E.

15. 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 F.

16. Pursuant to 21 U.S.C. § 355(b)(1), the '724 patent, the '725 patent, the '424 patent, the '981 patent, the '218 patent, and the '219 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. Plaintiffs reallege paragraphs 1-16 as if fully set forth herein.

18. Upon information and belief, Defendant submitted ANDA No. 205048 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 205048 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 the '724 patent. ANDA No. 205048 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 '724 patent.

19. Upon information and belief, ANDA No. 205048 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. Defendant notified Plaintiffs 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. Defendant's submission to the FDA of ANDA No. 205048, including the § 505(j)(2)(A)(vii)(IV) certification seeking FDA approval prior to expiration of the '724 patent, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

21. Defendant's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 205048 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. Plaintiffs are entitled to a declaration that, if Defendant 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, Defendant would infringe the '724 patent under 35 U.S.C. § 271(a), (b), and/or (c).

23. Plaintiffs will be irreparably harmed by Defendant'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 '725 PATENT

24. Plaintiffs reallege paragraphs 1-23 as if fully set forth herein.

25. Upon information and belief, Defendant submitted ANDA No. 205048 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 205048 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 the '725 patent. ANDA No. 205048 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 '725 patent.

26. Upon information and belief, ANDA No. 205048 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. Defendant notified Plaintiffs 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.

27. Defendant's submission to the FDA of ANDA No. 205048, including the § 505(j)(2)(A)(vii)(IV) certification seeking FDA approval prior to expiration of the '725 patent, constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

28. Defendant's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 205048 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

29. Plaintiffs are entitled to a declaration that, if Defendant 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, Defendant would infringe the '725 patent under 35 U.S.C. § 271(a), (b), and/or (c).

30. Plaintiffs will be irreparably harmed by Defendant'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 '424 PATENT

31. Plaintiffs reallege paragraphs 1-30 as if fully set forth herein.

32. Upon information and belief, Defendant submitted ANDA No. 205048 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 205048 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 the '424 patent.

ANDA No. 205048 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 '424 patent.

33. Upon information and belief, ANDA No. 205048 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. Defendant notified Plaintiffs 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.

34. Defendant's submission to the FDA of ANDA No. 205048, including the § 505(j)(2)(A)(vii)(IV) certification seeking FDA approval prior to expiration of the '424 patent, constitutes infringement of the '424 patent under 35 U.S.C. § 271(e)(2)(A).

35. Defendant's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 205048 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '424 patent under 35 U.S.C. § 271(e)(2)(A).

36. Plaintiffs are entitled to a declaration that, if Defendant 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, Defendant would infringe the '424 patent under 35 U.S.C. § 271(a), (b), and/or (c).

37. Plaintiffs will be irreparably harmed by Defendant'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 '981 PATENT

38. Plaintiffs reallege paragraphs 1-37 as if fully set forth herein.

39. Upon information and belief, Defendant submitted ANDA No. 205048 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 205048 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 the '981 patent. ANDA No. 205048 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 '981 patent.

40. Upon information and belief, ANDA No. 205048 includes a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '981 patent are invalid. Defendant notified Plaintiffs 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 '981 patent, separate and apart from its assertions that those claims are allegedly invalid.

41. Defendant's submission to the FDA of ANDA No. 205048, including the § 505(j)(2)(A)(vii)(IV) certification seeking FDA approval prior to expiration of the '981 patent, constitutes infringement of the '981 patent under 35 U.S.C. § 271(e)(2)(A). Defendant's submission to the FDA of ANDA No. 205048, including the § 505(j)(2)(A)(vii)(IV) certification seeking FDA approval prior to expiration of the '981 patent, constitutes infringement of the '981 patent under 35 U.S.C. § 271(e)(2)(A).

42. Defendant's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 205048 and

the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '981 patent under 35 U.S.C. § 271(e)(2)(A).

43. Plaintiffs are entitled to a declaration that, if Defendant commercially manufactures, uses, offers for sale, or sell 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 induce or contribute to such conduct, Defendant would infringe the '981 patent under 35 U.S.C. § 271(a), (b), and/or (c).

44. Plaintiffs will be irreparably harmed by Defendant'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 '218 PATENT

45. Plaintiffs reallege paragraphs 1-44 as if fully set forth herein.

46. Upon information and belief, Defendant submitted ANDA No. 205048 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 205048 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 the '218 patent. ANDA No. 205048 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.

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

48. The '218 patent shares the same expiration date as the '724, '725, '424, and '981 patents. By seeking FDA approval of its ANDA No. 205048 prior to

expiration of the ’724, ’725,’424, and ’981 patents, Defendant necessarily seeks approval of that ANDA prior to expiration of the ’218 patent.

49. Upon information and belief, Defendant is required by law to either amend its ANDA to contain a § 505(j)(2)(A)(vii)(IV) certification with respect to the ’218 patent as well, or must relinquish its request that the FDA approve ANDA No. 205048 prior to the expiration of the ’218 patent.

50. Defendant’s submission to the FDA of ANDA No. 205048, seeking immediate approval without waiting for patent expiration, constitutes infringement of the ’218 patent under 35 U.S.C. § 271(e)(2)(A).

51. Defendant’s active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 205048 constitutes infringement of the ’218 patent under 35 U.S.C. § 271(e)(2)(A).

52. Plaintiffs are entitled to a declaration that, if Defendant commercially manufactures, uses, offers for sale, or sell 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, Defendant would infringe the ’218 patent under 35 U.S.C. § 271(a), (b), and/or (c).

53. Plaintiffs will be irreparably harmed by Defendant’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 ’219 PATENT

54. Plaintiffs reallege paragraphs 1-53 as if fully set forth herein.

55. Upon information and belief, Defendant submitted ANDA No. 205048 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 205048 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 the '219 patent. ANDA No. 205048 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.

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

57. The '219 patent shares the same expiration date as the '724, '725, '424, and '981 patents. By seeking FDA approval of its ANDA No. 205048 prior to expiration of the '724, '725, '424, and '981 patents, Defendant necessarily seeks approval of that ANDA prior to expiration of the '219 patent.

58. Upon information and belief, Defendant is required by law to either amend its ANDA to contain a § 505(j)(2)(A)(vii)(IV) certification with respect to the '219 patent as well, or must relinquish its request that the FDA approve ANDA No. 205048 prior to the expiration of the '219 patent.

59. Defendant's submission to the FDA of ANDA No. 205048, seeking immediate approval without waiting for patent expiration, constitutes infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

60. Defendant's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 205048 constitutes infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

61. Plaintiffs are entitled to a declaration that, if Defendant commercially manufactures, uses, offers for sale, or sell 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, Defendant would infringe the '219 patent under 35 U.S.C. § 271(a), (b), and/or (c).

62. Plaintiffs will be irreparably harmed by Defendant'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. Judgment be entered declaring that Defendant has infringed the '724, '725, '424, '981, '218, and '219 patents by submitting ANDA No. 205048;

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. 205048 be a date that is not earlier than the expiration dates of the '724, '725, '424, '981, '218, and '219 patents, or any later expiration of exclusivity for any of these patents to which Plaintiffs are or become entitled;

C. An Order be issued that Defendant, its officers, agents, servants, and employees, and those persons in active concert or participation with Defendant, 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, '725, '424, '981, '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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