

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

Plaintiffs,

v.

MYLAN, INC. and MYLAN
INSTITUTIONAL LLC,

Defendants.

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) C.A. No. _____
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COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Helsinn Healthcare S.A. (“Helsinn”) and Roche Palo Alto LLC (“Roche”) (collectively, “Plaintiffs”), for their Complaint against Defendants Mylan, Inc. and Mylan Institutional LLC (collectively, “Mylan” or “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 Mylan, Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317. Upon information and belief, Mylan, Inc., directly and/or through Mylan Institutional LLC, markets, manufactures, distributes, and sells generic drugs for use in the State of Delaware and throughout the United States.
4. Upon information and belief, Defendant Mylan Institutional LLC is a corporation organized and existing under the laws of the State of Delaware, with its principal

place of business at 4901 Hiawatha Drive, Rockford, IL 61103. Upon information and belief, Mylan Institutional LLC manufactures, markets, and/or sells various generic drug products for sale and use in the State of Delaware and throughout the United States, including generic pharmaceutical drugs manufactured by Mylan, Inc. Upon information and belief, Mylan Institutional LLC is a wholly owned subsidiary of Mylan, Inc.

5. Upon information and belief, the acts of Mylan Institutional LLC complained of herein were done at the direction of, with the authorization of, and with the cooperation, assistance, and/or participation of Mylan, Inc.

NATURE OF THE ACTION

6. 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

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 is an actual controversy within the Court’s jurisdiction.

9. 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).

10. 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.

11. This Court has personal jurisdiction over Mylan, Inc. by virtue of the fact that, *inter alia*, it: (1) engages in persistent conduct within Delaware, with and through its subsidiary Mylan Institutional LLC, a Delaware Corporation, including, upon information and belief, the preparation and submission of ANDA No. 206416; (2) has purposely availed itself of the privilege of doing business in this Judicial District including through, *inter alia*, Mylan Institutional LLC, a Delaware Corporation; (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; and (4) maintains extensive systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents through, *inter alia*, Mylan Institutional LLC.

12. This Court has personal jurisdiction over Mylan Institutional LLC by virtue of the fact that, *inter alia*, it: (1) is incorporated in Delaware; (2) engages in persistent conduct within Delaware, including, upon information and belief, the preparation and submission of ANDA No. 206416; (3) has purposely availed itself of the privilege of doing business in this Judicial District; (4) maintains extensive systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents; and (5) has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court.

THE PATENTS-IN-SUIT

13. 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.

14. 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.

15. 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.

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 D.

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

18. 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

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

20. Upon information and belief, Defendants submitted ANDA No. 206416 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 206416 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 '724 patent. ANDA No. 206416 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.

21. Upon information and belief, ANDA No. 206416 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. Defendants 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.

22. Defendants' submission to the FDA of ANDA No. 206416, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of '724 patent under 35 U.S.C. § 271(e)(2)(A).

23. Mylan, Inc. and Mylan Institutional LLC are jointly and severally liable for any infringement of the '724 patent. This is because, upon information and belief, Mylan, Inc. and Mylan Institutional LLC actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 206416 to the FDA.

24. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 206416 and the

§ 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

25. 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 '724 patent under 35 U.S.C. § 271(a), (b), and/or (c).

26. 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 '725 PATENT

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

28. Upon information and belief, Defendants submitted ANDA No. 206416 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 206416 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 '725 patent. ANDA No. 206416 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.

29. Upon information and belief, ANDA No. 206416 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. Defendants 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.

30. Defendants' submission to the FDA of ANDA No. 206416, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of '725 patent under 35 U.S.C. § 271(e)(2)(A).

31. Mylan, Inc. and Mylan Institutional LLC are jointly and severally liable for any infringement of the '725 patent. This is because, upon information and belief, Mylan, Inc. and Mylan Institutional LLC actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 206416 to the FDA.

32. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 206416 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

33. 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 '725 patent under 35 U.S.C. § 271(a), (b), and/or (c).

34. 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 III – INFRINGEMENT OF THE '424 PATENT

35. Plaintiffs reallege paragraphs 1-34 as if fully set forth herein.

36. Upon information and belief, Defendants submitted ANDA No. 206416 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 206416 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 '424 patent. ANDA No. 206416 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.

37. Upon information and belief, ANDA No. 206416 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. Defendants 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.

38. Defendants' submission to the FDA of ANDA No. 206416, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of '424 patent under 35 U.S.C. § 271(e)(2)(A).

39. Mylan, Inc. and Mylan Institutional LLC are jointly and severally liable for any infringement of the '424 patent. This is because, upon information and belief, Mylan, Inc. and Mylan Institutional LLC actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 206416 to the FDA.

40. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 206416 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '424 patent under 35 U.S.C. § 271(e)(2)(A).

41. 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 '424 patent under 35 U.S.C. § 271(a), (b), and/or (c).

42. 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 IV – INFRINGEMENT OF THE '219 PATENT

43. Plaintiffs reallege paragraphs 1-42 as if fully set forth herein.

44. Upon information and belief, Defendants submitted ANDA No. 206416 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 206416 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. 206416 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.

45. Upon information and belief, ANDA No. 206416 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. Defendants 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 '219 patent, separate and apart from its assertions that those claims are allegedly invalid.

46. Defendants' submission to the FDA of ANDA No. 206416, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of '219 patent under 35 U.S.C. § 271(e)(2)(A).

47. Mylan, Inc. and Mylan Institutional LLC are jointly and severally liable for any infringement of the '219 patent. This is because, upon information and belief, Mylan, Inc. and Mylan Institutional LLC actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 206416 to the FDA.

48. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 206416 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

49. 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).

50. 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 V – INFRINGEMENT OF THE '094 PATENT

51. Plaintiffs reallege paragraphs 1-50 as if fully set forth herein.

52. Upon information and belief, Defendants submitted ANDA No. 206416 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 206416 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 '094 patent. ANDA No. 206416 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 '094 patent.

53. The '094 patent had not been issued at the time Defendants made their § 505(j)(2)(A)(vii)(IV) certification regarding Plaintiffs' other Orange Book-listed patents.

54. The '094 patent shares the same expiration date as the '724, '725, '424, and '219 patents. By seeking FDA approval of its ANDA No. 206416 prior to expiration of the '724, '725, '424, and '219 patents, Defendants necessarily seek approval of that ANDA prior to expiration of the '094 patent.

55. 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 '094 patent, or must relinquish their request that the FDA approve ANDA No. 206416 prior to the expiration of the '094 patent.

56. Defendants' submission to the FDA of ANDA No. 206416, seeking immediate approval without waiting for patent expiration, constitutes infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

57. Mylan, Inc. and Mylan Institutional LLC are jointly and severally liable for any infringement of the '094 patent. This is because, upon information and belief, Mylan, Inc. and Mylan Institutional LLC actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 206416 to the FDA.

58. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 206416 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

59. 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 '094 patent under 35 U.S.C. § 271(a), (b), and/or (c).

60. 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:

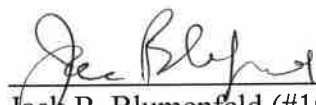
A. A Judgment be entered declaring that Defendants have infringed the '724, '725, '424, '219, and '094 patents by submitting ANDA No. 206416;

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. 206416 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 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 '724, '725, '424, '219, and '094 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.

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