

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACORDA THERAPEUTICS, INC. and
ALKERMES PHARMA IRELAND
LIMITED,

Plaintiffs,

V.

C.A. No. _____

ROXANE LABORATORIES, INC. and
BOEHRINGER INGELHEIM ROXANE,
INC.,

Defendants.

COMPLAINT

Acorda Therapeutics, Inc. (“Acorda”) and Alkermes Pharma Ireland Limited (“Alkermes” and together with Acorda, “Plaintiffs”), for their Complaint against Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc. (together, “Roxane” or “Defendant”), allege as follows:

NATURE OF THE ACTION

1. This is an action by Plaintiffs against Defendants for patent infringement of United States Patent Nos. 5,540,938 (the “’938 patent”), 8,007,826 (the “’826 patent”), 8,354,437 (the “’437 patent”), 8,440,703 (the “’703 patent”) and 8,663,685 (the “’685 patent”) (collectively, the “Ampyra® Patents”).

2. This action arises out of Defendants’ filing of Abbreviated New Drug Application (“ANDA”) No. 206646 seeking approval by the United States Food and Drug Administration (“FDA”) to sell generic copies of Acorda’s flagship drug product Ampyra[®], prior to the expiration of the Ampyra[®] Patents.

THE PARTIES

3. Acorda is a corporation organized under the laws of the State of Delaware and has its principal place of business located at 420 Saw Mill River Road, Ardsley, New York 10502. Acorda is engaged in the research, development, and sale of biotech and pharmaceutical products. Acorda invests extensively in designing and developing new and innovative therapies to restore neurological function and improve the lives of people with multiple sclerosis (“MS”), spinal cord injuries and other disorders of the nervous system. Ampyra[®] is the only treatment shown to improve walking in people with MS, which was demonstrated by an increase in walking speed.

4. Alkermes is an Irish corporation (company number 448848) having a principal place of business at Connaught House, 1 Burlington Road, Dublin 4, Ireland.

5. Alkermes is the assignee of the '938 patent. Acorda is the exclusive licensee in the U.S. to package, use, import, export, promote, distribute, offer for sale, sell and otherwise exploit the '938 patent for oral prescription medicine for the treatment of MS in humans. Acorda also has the right to initiate and prosecute legal action for infringement by a third-party of the '938 patent.

6. Acorda has all right, title, and interest in the '826 patent, '437 patent, '703 patent, and '685 patent, and the right to sue for infringement thereof.

7. On information and belief, defendant Roxane Laboratories, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228.

8. On information and belief, defendant Roxane Laboratories, Inc. is in the business of, among other things, formulating, developing, manufacturing, packaging, marketing, and

selling generic copies of branded pharmaceutical products for the United States market, including in Delaware. On information and belief, Roxane Laboratories, Inc. is the research and development, sales and marketing arm of the Boehringer Ingelheim group's multisource pharmaceutical business in the U.S. On information and belief, in 2012, Roxane Laboratories, Inc. received fourteen ANDA approvals and launched eleven generic drug products.

9. On information and belief, defendant Boehringer Ingelheim Roxane, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228, and having designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

10. On information and belief, defendant Boehringer Ingelheim Roxane, Inc. is the manufacturing arm for Roxane Laboratories, Inc. and manufactures pharmaceutical products including, among other things, sustained-release and controlled-release tablets for Roxane Laboratories, Inc.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over the Defendants.

13. This Court has personal jurisdiction over Defendants by virtue of the fact that, *inter alia*, they have committed — or aided, abetted, induced, contributed to, or participated in

the commission of — the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Acorda, a Delaware corporation, and to Alkermes.

14. This Court has personal jurisdiction over Roxane Laboratories, Inc. On information and belief Roxane Laboratories, Inc. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, through various directly- or indirectly-owned operating subsidiaries including Boehringer Ingelheim Roxane, Inc., and/or derives substantial revenue from services or things used or consumed by Roxane Laboratories, Inc. or its affiliates and agents, including Boehringer Ingelheim Roxane, Inc., in Delaware, demonstrating that Roxane Laboratories, Inc. has continuous and systemic contacts with Delaware.

15. On information and belief, defendant Roxane Laboratories, Inc. is in the business of, among other things, formulating, developing, manufacturing, packaging, marketing, and selling generic copies of branded pharmaceutical products for the United States market, including in Delaware. On information and belief, Roxane Laboratories, Inc. directly or through its affiliates and agents (including Boehringer Ingelheim Roxane, Inc.), formulates, manufactures, packages, markets, and/or sells pharmaceutical products throughout the United States and in Delaware.

16. On information and belief, Roxane Laboratories, Inc. has previously availed itself of this forum by submitting to the jurisdiction of this Court and asserting counterclaims in other civil actions initiated in this jurisdiction, including, for example, in *Teijin Ltd., et al. v. Roxane Laboratories, Inc.* (C.A. No. 1:14-cv-00189-SLR) (Doc. 16) and *Pfizer Inc., et al. v. Roxane Laboratories, Inc., et al.* (C.A. No. 1:12-cv-00813-SLR) (Doc. 13).

17. This Court has personal jurisdiction over Boehringer Ingelheim Roxane, Inc. On information and belief, Boehringer Ingelheim Roxane, Inc. is a corporation organized and existing under the laws of the State of Delaware, having designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

18. On information and belief, Boehringer Ingelheim Roxane, Inc. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware by Boehringer Ingelheim Roxane, Inc. or its affiliates and agents, including Roxane Laboratories, Inc., demonstrating that Boehringer Ingelheim Roxane, Inc. has continuous and systemic contacts with Delaware.

19. On information and belief, defendant Boehringer Ingelheim Roxane, Inc. is the manufacturing arm for Roxane Laboratories, Inc. and manufactures pharmaceutical products including, among other things, sustained-release and controlled-release tablets.

20. On information and belief, Defendants are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including into Delaware, including the dalfampridine extended release tablets described in Defendants' ANDA No. 206646 (the "Roxane Generic Tablets"), which are accused of infringing the Ampyra[®] Patents.

21. If ANDA No. 206646 is approved, the Roxane Generic Tablets will, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and

dispensed by pharmacies located within Delaware, all of which will have a substantial effect on Delaware.

22. Defendants know and intend that Roxane Generic Tablets will be distributed and sold in the United States, including in Delaware.

23. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

The '938 Patent

24. On July 30, 1996, the United States Patent and Trademark Office (“USPTO”) issued the '938 patent, titled “Formulations and Their Use in the Treatment of Neurological Diseases.” The '938 patent is duly and legally assigned to Alkermes. Acorda is the exclusive licensee in the U.S. to package, use, import, export, promote, distribute, offer for sale, sell and otherwise exploit the '938 patent for oral prescription medicine for the treatment of MS in humans. Acorda also has the right to initiate and prosecute legal action for infringement by a third-party of the '938 patent. A copy of the '938 patent is attached hereto as Exhibit A.

The '826 Patent

25. On August 30, 2011, the USPTO issued the '826 patent, titled “Sustained Release Aminopyridine Composition.” The '826 patent is duly and legally assigned to Acorda. A copy of the '826 patent is attached hereto as Exhibit B.

The '437 Patent

26. On January 15, 2013, the USPTO issued the '437 patent, titled “Method of Using Sustained Release Aminopyridine Compositions.” The '437 patent is duly and legally assigned to Acorda. A copy of the '437 patent is attached hereto as Exhibit C.

The '703 Patent

27. On May 14, 2013, the USPTO issued the '703 patent, titled "Methods of Using Sustained Release Aminopyridine Compositions." The '703 patent is duly and legally assigned to Acorda. A copy of the '703 patent is attached hereto as Exhibit D.

The '685 Patent

28. On March 4, 2014, the USPTO issued the '685 patent, titled "Sustained Release Aminopyridine Composition." The '685 patent is duly and legally assigned to Acorda. A copy of the '685 patent is attached hereto as Exhibit E.

Orange Book Listing for Ampyra[®]

29. Acorda holds an approved New Drug Application ("NDA"), No. 022250, for the use of 10 mg dalfampridine extended release tablets to improve walking in patients with multiple sclerosis, which Acorda sells under the registered name Ampyra[®].

30. The use of Ampyra[®] to improve walking in patients with MS is covered by the Ampyra[®] Patents.

31. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the Ampyra[®] Patents are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for improvement of walking in patients with MS.

32. The Orange Book lists the expiration dates for the '938 patent as July 30, 2018, the '826 patent as May 26, 2027, the '437 patent as December 22, 2026, the '703 patent as April 8, 2025, and the '685 patent as January 18, 2025.

ROXANE'S ANDA

33. By letter dated July 1, 2014 (the “Roxane Notice Letter”) and received by Plaintiffs on July 7, 2014, Roxane Laboratories, Inc. notified Plaintiffs that it had filed ANDA No. 206646 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act (“FDCA”) to market and sell Roxane Generic Tablets – generic copies of Ampyra[®] (10 mg dalfampridine extended release tablets) – “for the treatment of improving walking in patients with [MS] – which is demonstrated by an increase in walking speed,” prior to the expiration of the Ampyra[®] Patents.

34. The Roxane Notice Letter asserts that ANDA No. 206646 contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and that each of the Ampyra[®] Patents are “invalid and/or not infringed” by the manufacture, use, or sale of the Roxane Generic Tablets.

35. Upon information and belief, Defendants collaborated and acted in concert in the decision to file and the filing of ANDA No. 206646.

36. Upon information and belief, Defendants will distribute the Roxane Generic Tablets in the United States.

COUNT I
(Infringement of the '938 Patent)

37. The allegations of paragraphs 1-36 above are repeated and re-alleged as if set forth fully herein.

38. Pursuant to 35 U.S.C. § 271(e)(2)(A), Roxane's filing of ANDA No. 206646 seeking approval to market Roxane Generic Tablets is an act of infringement of one or more claims of the '938 patent entitling Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4),

including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206646 be a date which is not earlier than the expiration date of the '938 patent.

39. Roxane had knowledge of the '938 patent when it submitted ANDA No. 206646 to the FDA.

40. Upon information and belief, Roxane intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Roxane Generic Tablets with the proposed labeling. The use of Roxane Generic Tablets in accordance with and as directed by Roxane's proposed labeling would infringe one or more claims of the '938 patent.

41. Upon information and belief, Roxane intends to actively induce infringement of one or more claims of the '938 patent.

42. Upon information and belief, Roxane knows that Roxane Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '938 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

43. Upon information and belief, Roxane intends to contribute to the infringement of one or more claims of the '938 patent.

44. The foregoing actions by Roxane constitute and/or would constitute infringement of one or more claims of the '938 patent, active inducement of infringement of one or more claims of the '938 patent, and/or contribution to the infringement by others of one or more claims of the '938 patent.

45. Plaintiffs will be substantially and irreparably harmed if Roxane is not enjoined from infringing the '938 patent. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the '826 Patent)

46. The allegations of paragraphs 1-45 above are repeated and re-alleged as if set forth fully herein.

47. Pursuant to 35 U.S.C. § 271(e)(2)(A), Roxane's filing of ANDA No. 206646 seeking approval to market Roxane Generic Tablets is an act of infringement of one or more claims of the '826 patent entitling Acorda to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206646 be a date which is not earlier than the expiration date of the '826 patent.

48. Roxane had knowledge of the '826 patent when it submitted ANDA No. 206646 to the FDA.

49. Upon information and belief, Roxane intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Roxane Generic Tablets with the proposed labeling. The use of Roxane Generic Tablets in accordance with and as directed by Roxane's proposed labeling would infringe one or more claims of the '826 patent.

50. Upon information and belief, Roxane intends to actively induce infringement of one or more claims of the '826 patent.

51. Upon information and belief, Roxane knows that Roxane Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '826 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

52. Upon information and belief, Roxane intends to contribute to the infringement of one or more claims of the '826 patent.

53. The foregoing actions by Roxane constitute and/or would constitute infringement of one or more claims of the '826 patent, active inducement of infringement of one or more claims of the '826 patent, and/or contribution to the infringement by others of one or more claims of the '826 patent.

54. Acorda will be substantially and irreparably harmed if Roxane is not enjoined from infringing the '826 patent. Acorda has no adequate remedy at law.

COUNT III
(Infringement of the '437 Patent)

55. The allegations of paragraphs 1-54 above are repeated and re-alleged as if set forth fully herein.

56. Pursuant to 35 U.S.C. § 271(e)(2)(A), Roxane's filing of ANDA No. 206646 seeking approval to market Roxane Generic Tablets is an act of infringement of one or more claims of the '437 patent entitling Acorda to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206646 be a date which is not earlier than the expiration date of the '437 patent.

57. Roxane had knowledge of the '437 patent when it submitted ANDA No. 206646 to the FDA.

58. Upon information and belief, Roxane intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Roxane Generic Tablets with the proposed labeling. The use of Roxane Generic Tablets in accordance with and as directed by Roxane's proposed labeling would infringe one or more claims of the '437 patent.

59. Upon information and belief, Roxane intends to actively induce infringement of one or more claims of the '437 patent.

60. Upon information and belief, Roxane knows that Roxane Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '437 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

61. Upon information and belief, Roxane intends to contribute to the infringement of one or more claims of the '437 patent.

62. The foregoing actions by Roxane constitute and/or would constitute infringement of one or more claims of the '437 patent, active inducement of infringement of one or more claims of the '437 patent, and/or contribution to the infringement by others of one or more claims of the '437 patent.

63. Acorda will be substantially and irreparably harmed if Roxane is not enjoined from infringing the '437 patent. Acorda has no adequate remedy at law.

COUNT IV
(Infringement of the '703 Patent)

64. The allegations of paragraphs 1-63 above are repeated and re-alleged as if set forth fully herein.

65. Pursuant to 35 U.S.C. § 271(e)(2)(A), Roxane's filing of ANDA No. 206646 seeking approval to market Roxane Generic Tablets is an act of infringement of one or more claims of the '703 patent entitling Acorda to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206646 be a date which is not earlier than the expiration date of the '703 patent.

66. Roxane had knowledge of the '703 patent when it submitted ANDA No. 206646 to the FDA.

67. Upon information and belief, Roxane intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Roxane Generic Tablets with the proposed labeling. The use of Roxane Generic Tablets in accordance with and as directed by Roxane's proposed labeling would infringe one or more claims of the '703 patent.

68. Upon information and belief, Roxane intends to actively induce infringement of one or more claims of the '703 patent.

69. Upon information and belief, Roxane knows that Roxane Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '703 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

70. Upon information and belief, Roxane intends to contribute to the infringement of one or more claims of the '703 patent.

71. The foregoing actions by Roxane constitute and/or would constitute infringement of one or more claims of the '703 patent, active inducement of infringement of one or more claims of the '703 patent, and/or contribution to the infringement by others of one or more claims of the '703 patent.

72. Acorda will be substantially and irreparably harmed if Roxane is not enjoined from infringing the '703 patent. Acorda has no adequate remedy at law.

COUNT V
(Infringement of the '685 Patent)

73. The allegations of paragraphs 1-72 above are repeated and re-alleged as if set forth fully herein.

74. Pursuant to 35 U.S.C. § 271(e)(2)(A), Roxane's filing of ANDA No. 206646 seeking approval to market Roxane Generic Tablets is an act of infringement of one or more

claims of the '685 patent entitling Acorda to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206646 be a date which is not earlier than the expiration date of the '685 patent.

75. Roxane had knowledge of the '685 patent when it submitted ANDA No. 206646 to the FDA.

76. Upon information and belief, Roxane intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Roxane Generic Tablets with the proposed labeling. The use of Roxane Generic Tablets in accordance with and as directed by Roxane's proposed labeling would infringe one or more claims of the '685 patent.

77. Upon information and belief, Roxane intends to actively induce infringement of one or more claims of the '685 patent.

78. Upon information and belief, Roxane knows that Roxane Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '685 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

79. Upon information and belief, Roxane intends to contribute to the infringement of one or more claims of the '685 patent.

80. The foregoing actions by Roxane constitute and/or would constitute infringement of one or more claims of the '685 patent, active inducement of infringement of one or more claims of the '685 patent, and/or contribution to the infringement by others of one or more claims of the '685 patent.

81. Acorda will be substantially and irreparably harmed if Roxane is not enjoined from infringing the '685 patent. Acorda has no adequate remedy at law.

COUNT VI
(Induced Infringement)

82. The allegations of paragraphs 1-81 above are repeated and re-alleged as if set forth fully herein.

83. On information and belief, Boehringer Ingelheim Roxane, Inc. actively and knowingly caused to be submitted and/or assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 206646 to the FDA, knowing of the Ampyra® Patents.

84. The filing of the ANDA by Defendants through Roxane Laboratories, Inc. constituted direct infringement under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), defendant Boehringer Ingelheim Roxane, Inc. induced the infringement of the Ampyra® Patents by actively and knowingly causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 206646 to the FDA knowing that the submission of ANDA No. 206646 would constitute direct infringement of the Ampyra® Patents. Defendant Boehringer Ingelheim Roxane, Inc.'s knowing and purposeful activities causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 206646, knowing that its submission would constitute direct infringement, constitute induced infringement of the Ampyra® Patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

A. A judgment that Roxane's submission of ANDA No. 206646 was an act of infringement and that Roxane's making, using, offering to sell, selling or importing Roxane Generic Tablets prior to the expiration of the Ampyra® Patents will infringe, actively induce infringement and/or contribute to the infringement of each of the Ampyra® Patents;

B. A judgment that defendant Boehringer Ingelheim Roxane, Inc.'s knowing and purposeful activities causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 206646, knowing that its submission would constitute direct infringement, induced infringement of each of the Ampyra[®] Patents;

C. A judgment that the effective date of any FDA approval for Roxane to make, use offer for sale, sell, market, distribute, or import the Roxane Generic Tablets be no earlier than the dates on which the Ampyra[®] Patents expire, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. A permanent injunction enjoining Roxane, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing the Roxane Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the Ampyra[®] Patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

E. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiffs to an award of its reasonable attorneys' fees for bringing and prosecuting this action;

F. An award of Plaintiffs' costs and expenses in this action;

G. Such further and additional relief as this Court deems just and proper.

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/s/ Maryellen Noreika

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