

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ACORDA THERAPEUTICS, INC. and )  
ALKERMES PHARMA IRELAND )  
LIMITED, )  
)  
Plaintiffs, )  
)  
v. ) C.A. No. \_\_\_\_\_  
)  
APOTEX CORP. and APOTEX INC., )  
)  
Defendants. )

**COMPLAINT**

Acorda Therapeutics, Inc. (“Acorda”) and Alkermes Pharma Ireland Limited (“Alkermes” and together with Acorda, “Plaintiffs”), for their Complaint against Apotex Inc. and Apotex Corp. (together, “Apotex” or “Defendants”), 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<sup>®</sup> Patents”).

2. This action arises out of Defendants’ filing of Abbreviated New Drug Application (“ANDA”) No. 206823 seeking approval by the United States Food and Drug Administration (“FDA”) to sell generic copies of Acorda’s flagship drug product Ampyra<sup>®</sup>, prior to the expiration of the Ampyra<sup>®</sup> 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<sup>®</sup> 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 Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

8. On information and belief, defendant Apotex Inc. is a corporation organized and existing under the laws of the Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

**JURISDICTION AND VENUE**

9. 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.

10. 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.

11. 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.

12. This Court has personal jurisdiction over Apotex Corp. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware.

13. On information and belief, Apotex Corp. is in the business of, among other things, formulating, developing, manufacturing, marketing, and selling generic copies of branded pharmaceutical products for the United States market, including in Delaware.

14. On information and belief, Apotex Corp. is registered to do business with the Delaware Department of State, Division of Corporations.

15. On information and belief, Apotex Corp. has designated a registered agent in Delaware as The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

16. On information and belief, Apotex Corp. is registered with the Delaware Board of Pharmacy, pursuant to Del. Code tit. 24, § 2540, as a licensed “Pharmacy - Wholesale” (License No. A4-0001921) and “Distributor/Manufacturer CSR” (License No. DM-0008873).

17. On information and belief, Apotex Corp. 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 Apotex Corp. or its affiliates and agents, including Apotex Inc., demonstrating that Apotex Corp. has continuous and systemic contacts with Delaware.

18. On information and belief, Apotex Corp. is an agent, affiliate, or subsidiary of Apotex, Inc., including for Apotex’s ANDA No. 206823.

19. On information and belief, Apotex Corp. is a wholly-owned affiliate of Apotex Inc.

20. On information and belief, Apotex Corp. has previously availed itself of this forum by initiating civil actions in this jurisdiction, including, for example, *Apotex Inc. et al. v. Senju Pharmaceutical Co. Ltd. et al.*, C.A. No. 1:12-cv-00196-SLR (D. Del. Feb. 16, 2012) (Doc. 1) and *Apotex Inc., et al. v. Pfizer Inc., et al.*, C.A. No. 1:03-cv-00990-SLR (D. Del.).

21. On information and belief, Apotex Corp. 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 *Bristol-Myers Squibb Co. v. Apotex Inc. et al.*, C.A. No. 1:14-cv-00351-RGA (D. Del. June 17, 2014) (Doc. 6) and *UCB Inc. et al v. Apotex Corp. et al.*, C.A. No. 1:13-cv-01209-LPS (D. Del. Sept. 9, 2013) (Doc. 12).

22. This Court has personal jurisdiction over Apotex Inc. On information and belief, Apotex Inc., directly or through various directly- or indirectly-owned operating subsidiaries or

affiliates, including through Apotex Corp., develops, formulates, manufactures, markets, and sells pharmaceutical drug products, including generic drug products, throughout the United States including in Delaware.

23. On information and belief Apotex 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 or affiliates, including Apotex Corp., and/or derives substantial revenue from services or things used or consumed by Apotex Inc. or its affiliates and agents, including Apotex Corp., in Delaware, demonstrating that Apotex Inc. has continuous and systemic contacts with Delaware.

24. On information and belief, the growth and success of Apotex Inc. is dependent upon, *inter alia*, the success of its affiliates and subsidiaries, including Apotex Corp. For example, Apotex states on its website that: “Apotex Inc. serves a marketplace of over 115 countries, and is committed to growth on a global basis through affiliates such as Apotex Corp. in the United States of America.” *Careers*, <http://www.apotex.com/us/en/careers/default.asp> (last visited July 16, 2014).

25. On information and belief, Apotex Inc. has previously availed itself of this forum by initiating civil actions in this jurisdiction, including, for example, *Apotex Inc. et al. v. Senju Pharmaceutical Co. Ltd. et al.*, C.A. No. 1:12-cv-00196-SLR (D. Del. Feb. 16, 2012) (Doc. 1) and *Apotex Inc., et al. v. Pfizer Inc., et al.*, C.A. No. 1:03-cv-00990-SLR (D. Del.).

26. On information and belief, Apotex 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 *Bristol-Myers Squibb Co. v. Apotex Inc. et*

*al.*, C.A. No. 1:14-cv-00351-RGA (D. Del. June 17, 2014) (Doc. 6) and *UCB Inc. et al v. Apotex Corp. et al.*, C.A. No. 1:13-cv-01209-LPS (D. Del. Sept. 9, 2014) (Doc. 12).

27. On information and belief, Apotex Inc. and Apotex Corp. share the domain name, [www.apotex.com](http://www.apotex.com). Users can access Apotex Corp.'s United States specific website (<http://www.apotex.com/us/en/>) via Apotex Inc.'s global website (<http://www.apotex.com/global/default.asp>) by selecting the "United States" as the country of interest.

28. On information and belief, Apotex Inc.'s global website solicits customers in Delaware and the United States by, *inter alia*: (1) directing customers and potential customers to Apotex's United States product list, *Products*, <http://www.apotex.com/global/products/default.asp> (last visited July 16, 2014); and (2) providing customers and potential customers a link to email Apotex's "United States Sales Contacts" regarding "Sales Inquiries," *Contact Us*, <http://www.apotex.com/global/contact/default.asp> (last visited July 16, 2014).

29. On information and belief, Apotex Corp.'s website solicits customers in Delaware and the United States by, *inter alia*: (1) providing customers and potential customers Apotex's United States product list, *Products*, <http://www.apotex.com/us/en/products/default.asp> (last visited July 16, 2014); and (2) providing customers and potential customers a link to email Apotex's "United States Sales Contacts" regarding "Sales Inquiries," *Contact Us*, <http://www.apotex.com/us/en/contact/default.asp> (last visited July 16, 2014).

30. 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 Apotex's ANDA

No. 206823 (the “Apotex Generic Tablets”), which are accused of infringing the Ampyra<sup>®</sup> Patents.

31. On information and belief, Apotex Inc. and Apotex Corp. have directors and officers in common. For example, on information and belief, Dr. Bernard Sherman serves as Chairman of the Board of both Apotex Inc. and Apotex Corp.

32. If ANDA No. 206823 is approved, the Apotex 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.

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

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

## **BACKGROUND**

### **The '938 Patent**

35. 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**

36. 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**

37. 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**

38. 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**

39. 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<sup>®</sup>**

40. 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<sup>®</sup>.

41. The use of Ampyra<sup>®</sup> to improve walking in patients with MS is covered by the Ampyra<sup>®</sup> Patents.



42. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the Ampyra<sup>®</sup> 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.

43. 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.

#### **APOTEX’S ANDA**

44. By letter dated July 11, 2014 (the “Apotex Notice Letter”) and received by Plaintiffs on July 15, 2014, Apotex Inc. notified Plaintiffs that it had filed ANDA No. 206823 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act (“FDCA”) to market and sell Apotex Generic Tablets – generic copies of Ampyra<sup>®</sup> (10 mg dalfampridine extended release tablets) – prior to the expiration of the Ampyra<sup>®</sup> Patents.

45. The Apotex Notice Letter asserts that ANDA No. 206823 contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and that each of the Ampyra<sup>®</sup> Patents are “invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the” Apotex Generic Tablets.

46. The Apotex Notice Letter also states that ANDA No. 206823 was submitted to the FDA and contains a Paragraph IV certification seeking “approval to engage in the commercial manufacture, use, or sale of [Apotex Generic Tablets] prior to expiration of [the Ampyra<sup>®</sup> Patents].”

47. The Apotex Notice Letter lists the applicant for ANDA No. 206823 as Apotex Inc., whose place of business is in Canada. The Apotex Notice Letter fails to list the name and

address of an agent in the United States authorized to accept service of process for the applicant. Accordingly, the Apotex Notice Letter fails to comply with 21 C.F.R. § 314.95(c)(7).

48. Upon information and belief, Defendants collaborated and acted in concert in the decision to file and the filing of ANDA No. 206823.

49. Upon information and belief, Defendants will distribute the Apotex Generic Tablets in the United States.

**COUNT I**  
**(Infringement of the '938 Patent)**

50. The allegations of paragraphs 1-49 above are repeated and re-alleged as if set forth fully herein.

51. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex's filing of ANDA No. 206823 seeking approval to market Apotex 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. 206823 be a date which is not earlier than the expiration date of the '938 patent.

52. Apotex had knowledge of the '938 patent when it submitted ANDA No. 206823 to the FDA.

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

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

55. Upon information and belief, Apotex knows that Apotex 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.

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

57. The foregoing actions by Apotex 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.

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

**COUNT II**  
**(Infringement of the '826 Patent)**

59. The allegations of paragraphs 1-58 above are repeated and re-alleged as if set forth fully herein.

60. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex's filing of ANDA No. 206823 seeking approval to market Apotex 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. 206823 be a date which is not earlier than the expiration date of the '826 patent.

61. Apotex had knowledge of the '826 patent when it submitted ANDA No. 206823 to the FDA.

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

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

64. Upon information and belief, Apotex knows that Apotex 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.

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

66. The foregoing actions by Apotex 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.

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

**COUNT III**  
**(Infringement of the '437 Patent)**

68. The allegations of paragraphs 1-67 above are repeated and re-alleged as if set forth fully herein.

69. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex's filing of ANDA No. 206823 seeking approval to market Apotex 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. 206823 be a date which is not earlier than the expiration date of the '437 patent.

70. Apotex had knowledge of the '437 patent when it submitted ANDA No. 206823 to the FDA.

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

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

73. Upon information and belief, Apotex knows that Apotex 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.

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

75. The foregoing actions by Apotex 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.

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

**COUNT IV**  
**(Infringement of the '703 Patent)**

77. The allegations of paragraphs 1-76 above are repeated and re-alleged as if set forth fully herein.

78. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex's filing of ANDA No. 206823 seeking approval to market Apotex 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. 206823 be a date which is not earlier than the expiration date of the '703 patent.

79. Apotex had knowledge of the '703 patent when it submitted ANDA No. 206823 to the FDA.

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

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

82. Upon information and belief, Apotex knows that Apotex 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.

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

84. The foregoing actions by Apotex 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.

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

**COUNT V**  
**(Infringement of the '685 Patent)**

86. The allegations of paragraphs 1-85 above are repeated and re-alleged as if set forth fully herein.

87. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex's filing of ANDA No. 206823 seeking approval to market Apotex 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. 206823 be a date which is not earlier than the expiration date of the '685 patent.

88. Apotex had knowledge of the '685 patent when it submitted ANDA No. 206823 to the FDA.

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

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

91. Upon information and belief, Apotex knows that Apotex 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.

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

93. The foregoing actions by Apotex 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.

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

**COUNT VI**  
**(Induced Infringement)**

95. The allegations of paragraphs 1-94 above are repeated and re-alleged as if set forth fully herein.

96. On information and belief, Apotex Corp. actively and knowingly caused to be submitted and/or assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 206823 to the FDA, knowing of the Ampyra® Patents.

97. The filing of the ANDA by Defendants through Apotex Inc. constituted direct infringement under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), defendant Apotex Corp. 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. 206823 to the FDA knowing that the submission of ANDA No.



206823 would constitute direct infringement of the Ampyra<sup>®</sup> Patents. Defendant Apotex Corp.'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. 206823, knowing that its submission would constitute direct infringement, constitute induced infringement of the Ampyra<sup>®</sup> Patents.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs request the following relief:

A. A judgment that Apotex's submission of ANDA No. 206823 was an act of infringement and that Apotex's making, using, offering to sell, selling or importing Apotex Generic Tablets prior to the expiration of the Ampyra<sup>®</sup> Patents will infringe, actively induce infringement and/or contribute to the infringement of each of the Ampyra<sup>®</sup> Patents;

B. A judgment that defendant Apotex Corp.'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. 206823, knowing that its submission would constitute direct infringement, induced infringement of each of the Ampyra<sup>®</sup> Patents;

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

D. A permanent injunction enjoining Apotex, 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 Apotex Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the Ampyra<sup>®</sup> 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Maryellen Noreika*

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Jack B. Blumenfeld (#1014)  
 Maryellen Noreika (#3208)  
 1201 North Market Street  
 P.O. Box 1347  
 Wilmington, DE 19899-1347  
 (302) 658-9200  
 jblumenfeld@mnat.com  
 mnoreika@mnat.com

OF COUNSEL:

*Attorneys for Acorda Therapeutics, Inc. and Alkermes Pharma Ireland Limited*

Aaron Stiefel  
 Daniel P. DiNapoli  
 Benjamin C. Hsing  
 Soumitra Deka  
 KAYE SCHOLER LLP  
 425 Park Avenue  
 New York, NY 10022  
 (212) 836-8000

Sylvia M. Becker  
 KAYE SCHOLER LLP  
 The McPherson Building  
 901 Fifteenth Street, NW  
 Washington, DC 20005-2327  
 (202) 683-3500

Anthony Michael  
 ACORDA THERAPEUTICS, INC.  
 420 Saw Mill River Road  
 Ardsley, NY 10502  
 (914) 326-6825

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