IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACORDA THERAPEUTICS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
PAR PHARMACEUTICAL, INC.,	)	
	)	
Defendant.	)	

COMPLAINT

Acorda Therapeutics, Inc. ("Acorda" or "Plaintiff"), for its Complaint against Par Pharmaceutical, Inc. ("Par" or "Defendant"), alleges as follows:

NATURE OF THE ACTION

1. This is an action by Acorda against Par for infringement of United States Patent Nos. 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 Par's filing of Abbreviated New Drug Application ("ANDA") No. 206847 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. Acorda has all right, title, and interest in the Ampyra Patents and the right to sue for infringement thereof.

5. On information and belief, defendant Par is a company organized and existing under the laws of Delaware, having its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977.

6. On information and belief, Par is in the business of manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in Delaware. On information and belief, Par directly or through its affiliates and agents develops, formulates, manufactures, markets, and sells pharmaceutical products throughout the United States, including in this judicial district. On information and belief, Par is registered with the Delaware Board of Pharmacy as a licensed "Distributor/Manufacturer CSR" (License No. DM-0009385) and as a licensed "Pharmacy – Wholesale" (License No. A4-0002001). On information and belief, Par has a registered agent for service of process at The Corporate Trust Company, Corporation Trust Center, Wilmington, Delaware 19801.

JURISDICTION AND VENUE

7. 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.

8. Par is subject to personal jurisdiction in Delaware due to its being a Delaware Corporation and by virtue of the fact that, *inter alia*, it has 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. Acorda is a Delaware corporation.

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

BACKGROUND

The '826 Patent

10. On August 30, 2011, the United States Patent and Trademark Office ("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 A.

The '437 Patent

11. 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 B.

The '703 Patent

12. 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 C.

The '685 Patent

13. 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 D.

Orange Book Listing for Ampyra®

14. 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.

15. The use of Ampyra to improve walking in patients with MS is covered by the Ampyra Patents.

16. 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.

17. The Orange Book lists the expiration dates for 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.

Par's ANDA

18. By letter dated September 10, 2015 (the "Par Notice Letter"), Par notified Acorda that it had filed ANDA No. 206847 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Par Generic Tablets — generic copies of Ampyra (10 mg dalfampridine extended release tablets) — to improve walking in patients with MS, prior to the expiration of the Ampyra Patents.

19. The Par Notice Letter states that ANDA No. 206847 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '826 patent, the '437 patent, the '703 patent, and the '685 patent are "invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the product" described in Par's ANDA.

20. The Par Notice Letter also states that ANDA No. 206847 was submitted to the FDA and contains a Paragraph IV certification "to obtain approval to engage in the commercial manufacture, use, or sale of [Par Generic Tablets] before the expiration date[s] of [the Ampyra Patents]."

21. Upon information and belief, Defendant will distribute the Par Generic Tablets in the United States.

COUNT I
(Infringement of the '826 Patent)

22. The allegations of paragraphs 1-21 above are repeated and re-alleged as if set forth fully herein.

23. Pursuant to 35 U.S.C. § 271(e)(2)(A), Par's filing of ANDA No. 206847 seeking approval to market Par 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. 206847 be a date which is not earlier than the expiration date of the '826 patent.

24. Par had knowledge of the '826 patent when it submitted ANDA No. 206847 to the FDA.

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

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

27. Upon information and belief, Par knows that Par 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 Par Generic Tablets and the proposed labeling are not suitable for any substantial non-infringing use.

28. Upon information and belief, Par intends to contribute to the infringement of one or more claims of the ’826 patent.

29. The foregoing actions by Par 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.

30. Acorda will be substantially and irreparably harmed if Par is not enjoined from infringing the ’826 patent. Acorda has no adequate remedy at law.

COUNT II
(Infringement of the ’437 Patent)

31. The allegations of paragraphs 1-30 above are repeated and re-alleged as if set forth fully herein.

32. Pursuant to 35 U.S.C. § 271(e)(2)(A), Par’s filing of ANDA No. 206847 seeking approval to market Par 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. 206847 be a date which is not earlier than the expiration date of the ’437 patent.

33. Par had knowledge of the ’437 patent when it submitted ANDA No. 206847 to the FDA.

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

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

36. Upon information and belief, Par knows that Par 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.

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

38. The foregoing actions by Par 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.

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

COUNT III
(Infringement of the '703 Patent)

40. The allegations of paragraphs 1-39 above are repeated and re-alleged as if set forth fully herein.

41. Pursuant to 35 U.S.C. § 271(e)(2)(A), Par's filing of ANDA No. 206847 seeking approval to market Par 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. 206847 be a date which is not earlier than the expiration date of the ’703 patent.

42. Par had knowledge of the ’703 patent when it submitted ANDA No. 206847 to the FDA.

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

44. Upon information and belief, Par intends to actively induce infringement of one or more claims of the ’703 patent.

45. Upon information and belief, Par knows that Par 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.

46. Upon information and belief, Par intends to contribute to the infringement of one or more claims of the ’703 patent.

47. The foregoing actions by Par 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.

48. Acorda will be substantially and irreparably harmed if Par is not enjoined from infringing the ’703 patent. Acorda has no adequate remedy at law.

COUNT IV
(Infringement of the ’685 Patent)

49. The allegations of paragraphs 1-48 above are repeated and re-alleged as if set forth fully herein.

50. Pursuant to 35 U.S.C. § 271(e)(2)(A), Par’s filing of ANDA No. 206847 seeking approval to market Par 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. 206847 be a date which is not earlier than the expiration date of the ’685 patent.

51. Par had knowledge of the ’685 patent when it submitted ANDA No. 206847 to the FDA.

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

53. Upon information and belief, Par intends to actively induce infringement of one or more claims of the ’685 patent.

54. Upon information and belief, Par knows that Par 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.

55. Upon information and belief, Par intends to contribute to the infringement of one or more claims of the ’685 patent.

56. The foregoing actions by Par 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.

57. Acorda will be substantially and irreparably harmed if Par is not enjoined from infringing the ’685 patent. Acorda has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Acorda requests the following relief:

A. A judgment that Par’s submission of ANDA No. 206847 was an act of infringement and that Defendant’s making, using, offering to sell, selling or importing Par 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 the effective date of any FDA approval for Par to make, use, offer for sale, sell, market, distribute, or import the Par Generic Tablets be no earlier than the dates on which the Ampyra Patents expire, or any later expiration of exclusivity to which Acorda is or become entitled;

C. A permanent injunction enjoining Par, 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 Par 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 Acorda is or become entitled;

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

E. An award of Acorda's costs and expenses in this action;

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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