IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACORDA THERAPEUTICS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
SUN PHARMACEUTICAL INDUSTRIES LIMITED and SUN PHARMACEUTICAL INDUSTRIES, INC.,	)	
	)	
Defendants.	)	

COMPLAINT

Acorda Therapeutics, Inc. ("Acorda" or "Plaintiff"), for its Complaint against Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. (collectively, "Sun" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is an action by Acorda against Sun 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 Sun's filing of Abbreviated New Drug Application ("ANDA") No. 208292 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 Sun Pharmaceutical Industries Limited is a company organized and existing under the laws of India, having its principal place of business at CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400063.

6. On information and belief, Sun is the 5th largest generic drug company in the U.S. with "one of the largest ANDAs pipeline (149 ANDAs awaiting approval)." On information and belief, Sun earned revenues of over $2 billion in 2014 from sales in the U.S. On information and belief, Sun has eight manufacturing facilities located in the U.S.

7. On information and belief, Sun manufactures and distributes generic pharmaceutical products in the U.S. through various related entities and subsidiaries, including defendant Sun Pharmaceutical Industries, Inc. On information and belief, Sun Pharmaceutical Industries, Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries Limited. On information and belief, the Defendants share common officers and directors. Sun Pharmaceutical Industries, Inc. is a Michigan corporation registered to conduct business in Delaware, and its registered agent is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. Sun Pharmaceutical Industries, Inc. holds

Delaware distributor/manufacturer CSR license nos. DM-0010549, DM-0010172, and DM-0010171. Sun Pharmaceutical Industries, Inc. holds Delaware pharmacy - wholesale license nos. A4-0002148, A4-0002109, and A4-0002107.

8. On information and belief, Sun 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, Sun directly or through its affiliates and agents (including Sun Pharmaceutical Industries, Inc.) develops, formulates, manufactures, markets, and sells pharmaceutical products throughout the United States and in this judicial district.

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. Acorda's claims arise out of and relate to Sun's activities that are, and will be, directed to Delaware. In particular, this suit arises out of Sun's filing of ANDA No. 208292 seeking FDA approval to sell dalfampridine extended release tablets (the "Sun Generic Tablets") in the United States including in Delaware. This suit further arises from Sun's sending a May 5, 2015 statutory notice letter (the "Sun Notice Letter") to Acorda, a Delaware corporation. When Sun sent the Sun Notice Letter to Acorda, Sun knew or should have known that Acorda is a Delaware corporation; that Acorda was already

litigating the Ampyra Patents in Delaware against other ANDA filers; and that Acorda would almost certainly sue Sun in Delaware within 45 days of receiving the Sun Notice Letter.

12. In addition, the Court has personal jurisdiction over the Defendants by virtue of their systematic and continuous contacts with the State of Delaware. For example:

- On information and belief, Sun is the 5th largest generic drug company in the U.S. with "one of the largest ANDAs pipeline (149 ANDAs awaiting approval)."
- On information and belief, Sun earned revenues of over $2 billion in 2014 from sales in the U.S. On information and belief, Sun has eight manufacturing facilities located in the U.S.
- On information and belief, Sun manufactures and distributes generic drugs in the U.S. through various related entities and subsidiaries, including defendant Sun Pharmaceutical Industries, Inc. On information and belief, Sun Pharmaceutical Industries, Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries Limited.
- Sun Pharmaceutical Industries, Inc. is a Michigan corporation registered to conduct business in Delaware, and its registered agent is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.
- Sun Pharmaceutical Industries, Inc. holds Delaware distributor/manufacturer CSR license nos. DM-0010549, DM-0010172, and DM-0010171.
- Sun Pharmaceutical Industries, Inc. holds Delaware pharmacy - wholesale license nos. A4-0002148, A4-0002109, and A4-0002107.

13. On information and belief, the Defendants share common officers and directors and 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 Sun Generic Tablets that would infringe the Ampyra Patents.

14. If ANDA No. 208292 is approved, the Sun 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.

15. Defendants know and intend that Sun Generic Tablets will be distributed and sold in the United States, including in Delaware. On information and belief, if ANDA No. 208292 is approved, Sun will manufacture Sun Generic Tablets for distribution throughout the United States, including in Delaware. On information and belief, Sun will distribute Sun Generic Tablets for sale and/or use in Delaware.

16. In addition, the Defendants have previously submitted to the jurisdiction of this Court and have further previously availed themselves of this Court by initiating lawsuits, consenting to this Court's jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Sun Pharmaceutical Industries Limited v. Wyeth*, No. 1:09-cv-00083-SLR (D. Del.) (Complaint filed by Sun Pharmaceutical Industries Limited); *AstraZeneca AB v. Sun Pharma Global FZE et al.*, No. 1:14-cv-00694-GMS (D. Del.) (D.I. 12) (Sun Pharmaceutical Industries Limited submitted counterclaims and did not contest jurisdiction); *Sanofi et al. v. Sun Pharma Global FZE et al.*, No. 1:14-cv-00294-RGA (D. Del.) (D.I. 19) (same); *Pfizer Inc. et al. v. Sun Pharma Global Inc. et al.*, No. 1:09-cv-00313-GMS (D. Del.) (D.I. 13) (Sun Pharmaceutical Industries, Inc. submitted counterclaims and did not contest jurisdiction).

17. In the alternative, this Court has jurisdiction over Sun Pharmaceutical Industries Limited under Federal Rule of Civil Procedure 4(k)(2)(A). Sun Pharmaceutical Industries Limited has contacts with the United States by, *inter alia*, having filed its ANDA with the FDA.

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

BACKGROUND

The ’826 Patent

19. 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

20. 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

21. 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

22. 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®

23. 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.

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

25. 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.

26. 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.

SUN'S ANDA

27. By sending the Sun Notice Letter, defendant Sun Pharmaceutical Industries Limited notified Acorda that it had filed ANDA No. 208292 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to market and sell Sun 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.

28. The Sun Notice Letter states that ANDA No. 208292 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 commercial manufacture, use or sale of the drug product described in Sun's ANDA."

29. The Sun Notice Letter also states that ANDA No. 208292 was submitted to the FDA and contains a Paragraph IV certification "to obtain approval to engage in the commercial manufacture, use or sale dalfampridine extended release tablets, 10 mg, before the expiration of the '826, '685, '437 and '703 patents."

30. Upon information and belief, Defendants collaborated and acted in concert in the decision to file and the filing of ANDA No. 208292.

31. Upon information and belief, Defendants will distribute the Sun Generic Tablets in the United States.

COUNT I
(Infringement of the '826 Patent)

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

33. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sun's filing of ANDA No. 208292 seeking approval to market Sun 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. 208292 be a date which is not earlier than the expiration date of the '826 patent.

34. Sun had knowledge of the '826 patent when it submitted ANDA No. 208292 to the FDA.

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

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

37. Upon information and belief, Sun knows that Sun 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 non-infringing use.

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

39. The foregoing actions by Sun 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.

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

COUNT II
(Infringement of the ’437 Patent)

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

42. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sun’s filing of ANDA No. 208292 seeking approval to market Sun 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. 208292 be a date which is not earlier than the expiration date of the ’437 patent.

43. Sun had knowledge of the ’437 patent when it submitted ANDA No. 208292 to the FDA.

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

45. Upon information and belief, Sun intends to actively induce infringement of one or more claims of the ’437 patent.

46. Upon information and belief, Sun knows that Sun 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.

47. Upon information and belief, Sun intends to contribute to the infringement of one or more claims of the ’437 patent.

48. The foregoing actions by Sun 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.

49. Acorda will be substantially and irreparably harmed if Sun is not enjoined from infringing the ’437 patent. Acorda has no adequate remedy at law.

COUNT III
(Infringement of the ’703 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), Sun’s filing of ANDA No. 208292 seeking approval to market Sun 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. 208292 be a date which is not earlier than the expiration date of the ’703 patent.

52. Sun had knowledge of the '703 patent when it submitted ANDA No. 208292 to the FDA.

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

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

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

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

57. The foregoing actions by Sun 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.

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

COUNT IV
(Infringement of the ’685 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), Sun’s filing of ANDA No. 208292 seeking approval to market Sun 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. 208292 be a date which is not earlier than the expiration date of the ’685 patent.

61. Sun had knowledge of the ’685 patent when it submitted ANDA No. 208292 to the FDA.

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

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

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

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

66. The foregoing actions by Sun 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.

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

COUNT V
(Induced Infringement)

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

69. On information and belief, defendant Sun Pharmaceutical Industries, Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 208292 to the FDA, knowing of the Ampyra Patents.

70. The filing of the ANDA by Defendants through Sun Pharmaceutical Industries Limited constituted direct infringement under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), defendant Sun Pharmaceutical Industries, 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. 208292 to the FDA knowing that the submission of ANDA No. 208292 would constitute direct infringement of the Ampyra Patents. Defendant Sun Pharmaceutical Industries, 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. 208292, knowing that its submission would constitute direct infringement, constitute induced infringement of the Ampyra Patents.

PRAYER FOR RELIEF

WHEREFORE, Acorda requests the following relief:

A. A judgment that Sun's submission of ANDA No. 208292 was an act of infringement and that Defendants making, using, offering to sell, selling or importing Sun 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 defendants Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. knowing and purposeful activities causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 208292, 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 Sun to make, use offer for sale, sell, market, distribute, or import the Sun 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;

D. A permanent injunction enjoining Sun, 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 Sun 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;

E. 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;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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