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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ACORDA THERAPEUTICS, INC., **Plaintiff,** **v.** **MICRO LABS LIMITED and MICRO LABS USA, INC.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT**

COMPLAINT

Acorda Therapeutics, Inc. ("Acorda" or "Plaintiff"), for its Complaint against Micro Labs Limited and Micro Labs USA, Inc. (collectively, "Micro Labs" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is an action by Acorda against Micro Labs 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 Micro Labs's filing of Abbreviated New Drug Application ("ANDA") No. 210158 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 approved by the FDA 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 Micro Labs Limited is a company organized and existing under the laws of India, having its principal place of business at 27, Race Course Road, Bangalore-560 001, India.

6. On information and belief, defendant Micro Labs USA, Inc. is a company organized and existing under the laws of New Jersey, having its principal place of business at 104 Carnegie Center, Suite 216, Princeton, New Jersey 08540. On information and belief, Micro Labs USA Inc. is a wholly owned subsidiary of Micro Labs Limited. On information and belief, Micro Labs USA Inc. is the U.S. agent for Micro Labs Limited.

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. Venue is proper in this Court under 28 U.S.C. §1400(b).

9. 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.

10. Acorda's claims arise out of and relate to Micro Labs's activities that are, and will be, directed to New Jersey. In particular, this suit arises out of Micro Labs's filing of ANDA No. 210158 seeking FDA approval to sell 10 mg dalfampridine extended release tablets (the "Micro Labs Generic Tablets") prior to the expiration of the '826,'437, '703, and '685 patents, throughout the United States, including in New Jersey. Micro Labs's infringing activities with respect to its filing of ANDA No. 210158 and its intent to commercialize and sell Micro Labs Generic Tablets has led and/or will lead to foreseeable harm and injury to Acorda.

11. In its ANDA and in the Notice Letter, Micro Labs Limited states that its authorized agent for its application for FDA approval of ANDA No. 210158 is Micro Labs USA, Inc. Micro Labs USA, Inc. is a New Jersey corporation, with a registered agent in this state.

12. On information and belief, Micro Labs USA, Inc. and Micro Labs Limited are agents of each other and/or work in concert with each other on the development, obtaining of regulatory approval, marketing, sale, and/or distribution of generic drugs, including Micro Labs Generic Tablets, throughout the United States, including in or into New Jersey. On information and belief, Micro Labs Limited directly, or through its subsidiary Micro Labs USA, Inc., manufactures, markets, imports, and sells generic drugs for distribution in New Jersey and throughout the United States. Micro Labs is licensed by the New Jersey Department of Health as a drug wholesaler under Registration Number 5004479.

13. Micro Labs maintains substantial, systematic, and continuous contacts throughout the United States, including with New Jersey. According to its website (www.microlabsltd.com; last accessed May 16, 2017), Micro Labs Limited has "established a strong presence in the USA" in conjunction with its "wholly owned subsidia[ry] in the USA (Micro Labs USA, Inc.)" to sell "all major dosages on most of the therapeutic [drug] segments. Micro Labs's website states that "Micro Labs USA, Inc. currently has six FDA approved generic products and has filed more than fifty ANDAs that are with the FDA at various stages of review and that "Micro Labs is planning to file ten to fifteen ANDAs annually" (http://www.microlabsusa.com/microlabsusa; last accessed May 10, 2017). Upon information and belief, Micro Labs Limited and Micro Labs USA, Inc. derive substantial revenue from generic pharmaceutical products that are sold, used, and/or consumed within New Jersey.

14. On information and belief, if ANDA No. 210158 is approved, Micro Labs, through its distribution channels, will direct sales of Micro Labs Generic Tablets into New Jersey. As a result, Micro Labs Generic Tablets will be marketed and distributed in New Jersey by Micro Labs, prescribed by physicians practicing in New Jersey, dispensed by pharmacies

located in New Jersey, and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

15. Micro Labs's filing of ANDA No. 210158 is related to this action, and has a substantial connection with New Jersey, because it is tied, in purpose and planned effect, to the deliberate making of sales and administration in New Jersey of Micro Labs Generic Tables, and this action is about whether that activity in New Jersey will infringe Acorda's Ampyra® Patents.

16. On information and belief, Micro Labs has previously availed itself of the jurisdiction of the United States District Court for the District of New Jersey by consenting to the personal jurisdiction and by filing counterclaims in other civil actions initiated in this Court. *See, e.g.*, *Bausch & Lomb Inc.* v. *Micro Labs USA, Inc.*, No. 1:15-cv-03113-NLH-JS (D.N.J.) (ECF No.16); *Bausch & Lomb Inc.* v. *Micro Labs USA, Inc.*, No. 1:14-cv-07406-NLH-JS (D.N.J.) (ECF No. 8); *Bausch & Lomb Inc.* v. *Micro Labs USA, Inc.*, No. 1:14-cv-01974-NLH-JS (D.N.J.) (ECF No. 10); *Takeda GmbH* v. *Micro Labs USA, Inc.*, No. 3:15-cv-07921-FLW-DEA (D.N.J.) (ECF No. 13); *Takeda GmbH* v. *Micro Labs USA, Inc.*, No. 3:15-cv-03376-FLW-DEA (D.N.J.) (ECF No. 11).

17. In the alternative, this Court has jurisdiction over Micro Labs Limited under Federal Rule of Civil Procedure 4(k)(2) because (a) Acorda's claims arise under federal law; (b) Micro Labs Limited is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Micro Labs Limited has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Micro Labs Limited satisfies due process. Micro Labs Limited also has contacts with the United States by having filed ANDA No. 210158, and others, with the FDA.

BACKGROUND

The '826 Patent

18. 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

19. 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

20. 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

21. 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®

22. 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 MS, which Acorda sells under the registered name Ampyra®.

23. The use of Ampyra® as directed in its product labeling to improve walking in patients with MS is covered by the Ampyra® Patents.

24. 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") in connection with Ampyra®.

25. 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.

Prior Litigation Relating to the Ampyra® Patents

26. In a decision dated March 31, 2017 in *Acorda Therapeutics, Inc.* v. *Roxane Labs., Inc.*, No. 14-882-LPS (ECF No. 285) ("March 17, 2017 Decision"), the United States District Court for the District of Delaware (Stark, J), held that claims 1, 7, 38, and 39 of the '826 patent, claims 3 and 5 of the '685 patent, claims 1, 2, 5, 22, 32, 36 and 37 of the '437 patent, and claims 36, 38, and 45 of the '703 patent were invalid for obviousness.

27. By notice of appeal dated May 23, 2017, Acorda has appealed from the March 31, 2017 Decision and the Delaware court's April 29, 2017 Judgment (ECF No. 289), to the United States Court of Appeals for the Federal Circuit.

28. The March 17, 2017 Decision did not address many claims of the Ampyra® Patents that are and will be infringed by Micro Labs filing of ANDA No. 210158 and, if approved by the FDA, its marketing and sale of Micro Labs Generic Tablets, including, *inter alia*, Claims 31 and 36 of the '826 patent, claim 4 of the '685 patent, claims 38-40 of the '437 patent, and claims 28, 30, 32 and 33 and 35 of the '703 patent.

Micro Labs's ANDA

29. By letter dated April 12, 2017 and received on April 13, 2017, (the "Micro Labs Notice Letter"), Micro Labs notified Acorda that it had filed ANDA No. 210158

with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Micro Labs 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.

30. The Micro Labs Notice Letter states that ANDA No. 210158 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the Ampyra® Patents are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product" described in ANDA No. 210158.

31. The Micro Labs Notice Letter also states that ANDA No. 210158 was submitted to the FDA and contains a Paragraph IV certification "to obtain approval to engage in the commercial manufacture, use or sale of dalfampridine tablet, 10 mg, before the expiration of the [Ampyra® Patents]."

32. The Micro Labs Notice Letter asserts that each of the claims of the Ampyra® Patents are invalid, but does not specifically contest infringement of any of the claims of those patents.

33. Upon information and belief, Defendants collaborated and acted in concert in the decision to file and the filing of ANDA No. 210158.

34. Upon information and belief, if ANDA No. 210158 is approved by the FDA, Defendants will market, distribute and sell Micro Labs Generic Tablets in the United States with their proposed labeling which will constitute infringement of the Ampyra® Patents.

COUNT I

(Infringement of the '826 Patent)

35. The allegations of paragraphs 1–34 above are repeated and re-alleged as if set forth fully herein.

36. Pursuant to 35 U.S.C. § 271(e)(2)(A), Micro Labs's filing of ANDA No. 210158 seeking approval to market Micro Labs Generic Tablets is an act of infringement of the 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. 210158 be a date which is not earlier than the expiration date of the '826 patent.

37. Micro Labs had knowledge of the '826 patent when it submitted ANDA No. 210158 to the FDA. This knowledge is reflected through the '826 patent's listing in the Orange Book in relation to Ampyra®, Micro Labs professed knowledge of prior litigation relating to the '826 patent, and the Micro Labs Notice Letter.

38. Upon information and belief, Micro Labs intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Micro Labs Generic Tablets with Micro Labs's proposed labeling. Pursuant to 21 U.S.C. § 505(j)(2)(A)(v), the FDA requires Micro Labs's proposed labeling for Micro Labs Generic Tablets to be materially the same as the labeling for Ampyra®. Thus, on information and belief, the conditions of use prescribed, recommended, or suggested for Micro Labs Generic Tablets in its proposed labeling are the same as those approved for Ampyra® and set forth in the Ampyra® drug label.

39. The use of Micro Labs Generic Tablets in accordance with and as directed by Micro Labs's proposed labeling would infringe one or more claims of the '826 patent. The claims of the '826 patent are directed to the improvement of walking or walking speed in MS patients by administering a 10 mg dalfampridine extended release tablet twice daily for a time period of at least two or at least 12 weeks to achieve certain pharmacokinetic results, where the 10 mg doses are the only doses of dalfampridine administered to the patient during that time period.

40. On information and belief, Micro Labs's proposed labeling for Micro Labs Generic Tablets states that the product " is indicated as a treatment to improve walking in patients with multiple sclerosis (MS) [as] demonstrated by an increase in walking speed . . . ." On information and belief, the proposed labeling also states that "[t]he maximum recommended dose of [Micro Labs Generic Tablets] is one 10 mg tablet twice daily, taken with or without food, and should not be exceeded," that "[d]oses should be taken approximately 12 hours apart," that "[p]atients should not take double or extra doses" and that "[n]o additional benefit was demonstrated at doses greater than 10 mg twice daily." On information and belief, it also states that "patients [should] not take . . . take more than 2 tablets in a 24 hour period." On information and belief, Micro Labs proposed labeling will instruct physicians that 10 mg extended release dalfampridine has been safely administered to MS patients for at least two weeks and for at least 12 weeks. On information and belief, in light of FDA bioequivalence and bioavailability requirements, administration of Micro Labs Generic Tablets according to Micro Labs proposed labeling will achieve pharmacokinetic parameters within the ranges claimed in the '826 patent.

41. On information and belief, Micro Labs Generic Tablets will generally be prescribed by physicians to patients with MS is accordance with Micro Labs's proposed labeling and those patients will self-administer the product as instructed by their prescribing physician. As a result, *inter alia*, of the contents described above, the proposed labeling distributed with Micro Labs Generic Tablets will encourage and instruct physicians to prescribe, and patients to administer the product in a manner that infringes one or more claims of the '826 patent.

42. Upon information and belief, Micro Labs intends to actively induce infringement of one or more claims of the '826 patent by marketing, distributing and/or selling its Micro Labs Generic Tablets with the proposed labeling.

43. Upon information and belief, Micro Labs knows that Micro Labs Generic Tablets and the proposed labeling are especially made or adapted for use in infringing the claims of the ’826 patent and that Micro Labs Generic Tablets and the proposed labeling are not suitable for any substantial non-infringing use.

44. Upon information and belief, Micro Labs intends to contribute to the infringement of one or more claims of the ’826 patent.

45. The foregoing actions by Micro Labs constitute and/or would constitute infringement of one or more claims of the ’826 patent, active inducement of infringement of at 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.

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

COUNT II

(Infringement of the ’437 Patent)

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

48. Pursuant to 35 U.S.C. § 271(e)(2)(A), Micro Labs’s filing of ANDA No. 210158 seeking approval to market Micro Labs Generic Tablets is an act of infringement of the 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. 210158 be a date which is not earlier than the expiration date of the ’437 patent.

49. Micro Labs had knowledge of the ’437 patent when it submitted ANDA No. 210158 to the FDA. This knowledge is reflected through the ’437 patent’s listing in the

Orange Book in relation to Ampyra®, Micro Labs professed knowledge of prior litigation relating to the '437 patent, and the Micro Labs Notice Letter.

50. Upon information and belief, Micro Labs intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Micro Labs Generic Tablets with Micro Labs's proposed labeling. Pursuant to 21 U.S.C. § 505(j)(2)(A)(v), the FDA requires Micro Labs's proposed labeling for Micro Labs Generic Tablets to be materially the same as the labeling for Ampyra®. Thus, on information and belief, the conditions of use prescribed, recommended, or suggested for Micro Labs Generic Tablets in its proposed labeling are the same as those approved for Ampyra® and set forth in the Ampyra® drug label.

51. The use of Micro Labs Generic Tablets in accordance with and as directed by Micro Labs's proposed labeling would infringe one or more claims of the '437 patent. The claims of the '437 patent are directed to the improvement of walking or walking speed in MS patients by administering a 10 mg dalfampridine extended release tablet twice daily for a time period of at least two or at least twelve weeks to achieve certain pharmacokinetic results, where the 10 mg doses are the only doses of dalfampridine administered to the patient during that time period.

52. On information and belief, Micro Labs's proposed labeling for Micro Labs Generic Tablets states that the product " is indicated as a treatment to improve walking in patients with multiple sclerosis (MS) [as] demonstrated by an increase in walking speed . . . ." On information and belief, the proposed labeling also states that "[t]he maximum recommended dose of [Micro Labs Generic Tablets is one 10 mg tablet twice daily, taken with or without food, and should not be exceeded," that "[d]oses should be taken approximately 12 hours apart," that "[p]atients should not take double or extra doses" and that "[n]o additional benefit was

demonstrated at doses greater than 10 mg twice daily." On information and belief, it also states that "patients [should] not take . . . take more than 2 tablets in a 24 hour period." On information and belief, Micro Labs proposed labeling will instruct physicians that 10 mg extended release dalfampridine has been safely administered to MS patients for at least two weeks and for at least 12 weeks. On information and belief, in light of FDA bioequivalence and bioavailability requirements, administration of Micro Labs Generic Tablets according to Micro Labs proposed labeling will achieve pharmacokinetic parameters within the ranges claimed in the '437 patent.

53. On information and belief, Micro Labs Generic Tablets will generally be prescribed by physicians to patients with MS is accordance with Micro Labs's proposed labeling and those patients will self-administer the product as instructed by their prescribing physician. As a result, *inter alia*, of the contents described above, the proposed labeling for Micro Labs Generic Tablets will encourage and instruct physicians to prescribe, and patients to administer the product in a manner that infringes one or more claims of the '437 patent.

54. Upon information and belief, Micro Labs intends to actively induce infringement of the claims of the '437 patent by marketing, distributing and/or selling its Micro Labs Generic Tablets with the proposed labeling.

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

56. Upon information and belief, Micro Labs intends to contribute to the infringement of one or more claims of the '437 patent.

57. The foregoing actions by Micro Labs 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.

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

COUNT III

(Infringement of the '703 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), Micro Labs's filing of ANDA No. 210158 seeking approval to market Micro Labs Generic Tablets is an act of infringement of the 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. 210158 be a date which is not earlier than the expiration date of the '703 patent.

61. Micro Labs had knowledge of the '703 patent when it submitted ANDA No. 210158 to the FDA. This knowledge is reflected through the '703 patent's listing in the Orange Book in relation to Ampyra®, Micro Labs professed knowledge of prior litigation relating to the '703 patent, and the Micro Labs Notice Letter.

62. Upon information and belief, Micro Labs intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Micro Labs Generic Tablets with Micro Labs's proposed labeling. Pursuant to 21 U.S.C. § 505(j)(2)(A)(v), the FDA requires Micro Labs's proposed labeling for Micro Labs Generic Tablets to be materially the same as the labeling for Ampyra®. Thus, on information and belief, the conditions of use prescribed,

recommended, or suggested for Micro Labs Generic Tablets in its proposed labeling are the same as those approved for Ampyra® and set forth in the Ampyra® drug label.

63. The use of Micro Labs Generic Tablets in accordance with and as directed by Micro Labs's proposed labeling would infringe at least the '703 Patent Asserted Claims. These claims are directed to the improvement of walking or walking speed in MS patients by administering a 10 mg dalfampridine extended release tablet twice daily for a time period of at least two or at least twelve weeks to achieve certain pharmacokinetic results, where the 10 mg doses are the only doses of dalfampridine administered to the patient during that time period.

64. On information and belief, Micro Labs's proposed labeling for Micro Labs Generic Tablets states that the product " is indicated as a treatment to improve walking in patients with multiple sclerosis (MS) [as] demonstrated by an increase in walking speed . . . ." On information and belief, the proposed labeling also states that "[t]he maximum recommended dose of [Micro Labs Generic Tablets is one 10 mg tablet twice daily, taken with or without food, and should not be exceeded," that "[d]oses should be taken approximately 12 hours apart," that "[p]atients should not take double or extra doses" and that "[n]o additional benefit was demonstrated at doses greater than 10 mg twice daily." On information and belief, it also states that "patients [should] not take . . . take more than 2 tablets in a 24 hour period." On information and belief, Micro Labs proposed labeling will instruct physicians that 10 mg extended release dalfampridine has been safely administered to MS patients for at least two weeks and for at least 12 weeks. On information and belief, in light of FDA bioequivalence and bioavailability requirements, administration of Micro Labs Generic Tablets according to Micro Labs proposed labeling will achieve pharmacokinetic parameters within the ranges claimed in the '703 patent.

65. On information and belief, Micro Labs Generic Tablets will generally be prescribed by physicians to patients with MS is accordance with Micro Labs's proposed labeling and those patients will self-administer the product as instructed by their prescribing physician. As a result, *inter alia*, of the contents described above, the proposed labeling for Micro Labs Generic Tablets will encourage and instruct physicians to prescribe, and patients to administer the product in a manner that infringes one or more claims of the '703 patent.

66. Upon information and belief, Micro Labs intends to actively induce infringement of the claims of the '703 patent by marketing, distributing and/or selling its Micro Labs Generic Tablets with the proposed labeling.

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

68. Upon information and belief, Micro Labs intends to contribute to the infringement of one or more claims of the '703 patent.

69. The foregoing actions by Micro Labs constitute and/or would constitute infringement of one or more claims of the '703 Patent Asserted Claims, 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.

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

COUNT IV

(Infringement of the '685 Patent)

71. The allegations of paragraphs 1–70 above are repeated and re-alleged as if set forth fully herein.

72. Pursuant to 35 U.S.C. § 271(e)(2)(A), Micro Labs's filing of ANDA No. 210158 seeking approval to market Micro Labs Generic Tablets is an act of infringement of the 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. 210158 be a date which is not earlier than the expiration date of the '685 patent.

73. Micro Labs had knowledge of the '685 patent when it submitted ANDA No. 210158 to the FDA. This knowledge is reflected through the '685 patent's listing in the Orange Book in relation to Ampyra®, Micro Labs professed knowledge of prior litigation relating to the '685 patent, and the Micro Labs Notice Letter.

74. Upon information and belief, Micro Labs intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Micro Labs Generic Tablets with Micro Labs's proposed labeling. Pursuant to 21 U.S.C. § 505(j)(2)(A)(v), the FDA requires Micro Labs's proposed labeling for Micro Labs Generic Tablets to be materially the same as the labeling for Ampyra®. Thus, on information and belief, the conditions of use prescribed, recommended, or suggested for Micro Labs Generic Tablets in its proposed labeling are the same as those approved for Ampyra® and set forth in the Ampyra® drug label.

75. The use of Micro Labs Generic Tablets in accordance with and as directed by Micro Labs's proposed labeling would infringe one or more claims of the '685 patent. These claims are directed to the improvement of walking or walking speed in MS patients by administering a 10 mg dalfampridine extended release tablet twice daily for a time

period of at least two or at least twelve weeks to achieve certain pharmacokinetic results, where the 10 mg doses are the only doses of dalfampridine administered to the patient during that time period.

76. On information and belief, Micro Labs's proposed labeling for Micro Labs Generic Tablets states that the product "is indicated as a treatment to improve walking in patients with multiple sclerosis (MS) [as] demonstrated by an increase in walking speed . . . ." On information and belief, the proposed labeling also states that "[t]he maximum recommended dose of [Micro Labs Generic Tablets is one 10 mg tablet twice daily, taken with or without food, and should not be exceeded," that "[d]oses should be taken approximately 12 hours apart," that "[p]atients should not take double or extra doses" and that "[n]o additional benefit was demonstrated at doses greater than 10 mg twice daily." On information and belief, it also states that "patients [should] not take . . . take more than two tablets in a 24 hour period." On information and belief, Micro Labs proposed labeling will instruct physicians that 10 mg extended release dalfampridine has been safely administered to MS patients for at least two weeks and for at least 12 weeks. On information and belief, in light of FDA bioequivalence and bioavailability requirements, administration of Micro Labs Generic Tablets according to Micro Labs proposed labeling will achieve pharmacokinetic parameters within the ranges claimed in the '685 patent.

77. On information and belief, Micro Labs Generic Tablets will generally be prescribed by physicians to patients with MS is accordance with Micro Labs's proposed labeling and those patients will self-administer the product as instructed by their prescribing physician. As a result, *inter alia*, of the contents described above, the proposed labeling for Micro Labs

Generic Tablets will encourage and instruct physicians to prescribe, and patients to administer the product in a manner that infringes one or more claims of the '685 patent.

78. Upon information and belief, Micro Labs intends to actively induce infringement of the '685 patent by marketing, distributing and/or selling its Micro Labs Generic Tablets with the proposed labeling.

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

80. Upon information and belief, Micro Labs intends to contribute to the infringement of one or more claims of the '685 patent.

81. The foregoing actions by Micro Labs 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.

82. Acorda will be substantially and irreparably harmed if Micro Labs 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 Micro Labs's submission of ANDA No. 210158 was an act of infringement and that Defendants' making, using, offering to sell, selling, or importing Micro Labs 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 Micro Labs to make, use, offer for sale, sell, market, distribute, or import Micro Labs 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 Micro Labs, their 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 Micro Labs 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; and

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

Dated: May 24, 2017

Respectfully submitted,

/s/ David E. De Lorenzi

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