

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FT. LAUDERDALE DIVISION**

CASE NO.: 0:13-cv-60742

ACCORD HEALTHCARE, INC. and
INTAS PHARMACEUTICALS LTD.,

Plaintiffs,

COMPLAINT

v.

ACORDA THERAPEUTICS, INC. and
H.D. SMITH WHOLESALE DRUG CO.,

Defendants.

Plaintiffs Accord Healthcare, Inc. and Intas Pharmaceuticals, Ltd. (collectively, "Accord Healthcare"), by way of Complaint and through its attorneys, brings this action against Defendant Acorda Therapeutics Inc. ("Acorda") and Defendant H.D. Smith Wholesale Drug Co. ("H.D. Smith") and allege as follows:

NATURE OF ACTION

1. Acorda is the manufacturer of Ampyra®, a brand-name drug containing the active ingredient dalfampridine. Ampyra® is the only drug with the active ingredient dalfampridine that is approved for marketing by FDA. Acorda therefore controls 100% of the commercial market for dalfampridine, a medication shown to improve walking in people with multiple sclerosis.

2. H.D. Smith is a distributor of Ampyra®, and is located at 1901 N.W. 25th Ave., Pompano Beach, Florida 33069.

3. As part of the approval process for an abbreviated new drug application ("ANDA") under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), the FDA requires an

applicant to conduct tests in order to demonstrate that its generic drug product is bioequivalent to the brand-name drug.

4. In order to develop a generic dalfampridine product, a drug manufacturer must therefore obtain samples of Ampyra®, the brand-name drug, to perform bioequivalence testing.

5. The unique regulatory framework that facilitates development and adoption of generic drugs in the United States depends on the ability of generic firms like Accord Healthcare to access samples of brand products in order to conduct the necessary testing to prepare its ANDA applications for submission to the FDA.

6. Acorda has abused its monopoly power by denying Accord Healthcare the ability to purchase Ampyra® samples for bioequivalence testing and to submit an ANDA to the FDA for a generic dalfampridine product.

7. As a result, Acorda has thwarted the market entry of any competing products, unlawfully maintaining its monopoly on dalfampridine in violation of Section 2 of the Sherman Act and Florida state law.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over this action, pursuant to 28 U.S.C. §§ 1331 and 1337, in that this action involves federal questions arising under Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26.

9. This Court further has subject matter jurisdiction pursuant to 28 U.S.C. §§ 2201(a) and 2202, since this case presents an actual, substantial, and justiciable controversy between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment, as fully explained herein.

10. In addition, this Court has supplemental jurisdiction over the Florida state law claims in this action pursuant to 28 U.S.C. § 1367, in that those claims are substantially related to the federal antitrust claims and therefore are part of the same case or controversy.

11. This Court has jurisdiction over Acorda because it is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products into this District. Acorda directly, or through its wholly-owned subsidiaries and agents, manufactures; markets; and sells Ampyra® in this District. Acorda is registered to do business in the State of Florida, and its registered agent for service is listed as residing in this District.

12. Acorda, either directly or through its agents, conducted or is conducting clinical trials of Ampyra® in this District at the University of Miami, and distributes Ampyra® through its agent or wholesale supplier, H.D. Smith, which resides in this District at Pompona Beach, Florida.

13. Venue is proper in this Court as to Defendants Acorda and H.D. Smith, pursuant to the provisions of 28 U.S.C. § 1391(b)(2), in that a substantial part of the events or omissions giving rise to this claim, specifically, Acorda's refusal to provide requested samples of Ampyra® through its agent and wholesaler H.D. Smith, occurred in this District.

THE PARTIES

14. Plaintiff Accord Healthcare Inc. is a corporation organized under the law of North Carolina, with a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

15. Plaintiff Intas Pharmaceuticals Ltd. is a corporation organized under the laws of India, with its principal place of business at Chinubhai Center Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

16. Defendant Acorda is a corporation organized and existing under the laws of the State of Delaware with its corporate headquarters at 15 Skyline Drive, Hawthorne, New York 10532. Upon information and belief, Acorda is engaged in the research, development and sale of biotech and pharmaceutical products.

17. Acorda manages the Ampyra® NDA and REMS in the United States, including in this Judicial District.

18. The website Ampyra.com provides that Ampyra® is marketed by Acorda Therapeutics, Inc.

19. Acorda maintains a registered agent in this Judicial district, and therefore reasonably anticipates being subject to the personal jurisdiction of this Court.

20. Defendant H.D. Smith is a corporation organized and existing under the laws of the State of Delaware with its principal business and corporate headquarters in Springfield, Illinois. The Florida Secretary of State lists H.D. Smith's current principal place of business as 1901 NW 25th Ave., Pompano Beach, Florida 33069. H.D. Smith is engaged in the distribution of prescription drugs, including Ampyra®.

STATUTORY AND REGULATORY BACKGROUND
FDA Approval for Brand-Name Drugs

21. Before marketing a new drug in the United States, a manufacturer must submit a new drug application ("NDA") to FDA, and FDA must approve it. Once approved, new drugs generally are referred to as brand-name drugs because they are marketed under a trade name or trademark for the drug product rather than under the chemical name of the drug product's active ingredient.

22. Among other things, an NDA must contain technical data on the composition of the drug product, including its active ingredient, the means for its manufacture and a statement of

its proposed uses. FDA approves a new drug only if it determines, based on evidence submitted by the manufacturer, that the drug is safe and effective for its proposed use(s).

The Hatch-Waxman Amendments and Generic Drugs

23. Congress enacted the Drug Price Competition & Patent Term Restoration Act, commonly known as the Hatch-Waxman Amendments ("Hatch-Waxman") to the FFDCA, to increase the availability of low-cost generic drugs by expediting the FDA approval process. In recognition of the competing interests of brand-name manufacturers, Hatch-Waxman also provided brand-name manufacturers with a valuable benefit. Under Hatch-Waxman, brand-name drug manufacturers became entitled to five years of exclusivity for new drugs and were given the ability to apply to extend the patent protection for their drugs by an additional five years. *See* 21 U.S.C. § 355(c)(3)(E)(ii); 35 U.S.C. § 156.

24. A generic drug is a version of a brand-name drug that contains the same active ingredient as the brand-name drug but typically sells at a lower cost than the brand-name drug.

25. Generic drugs are frequently prescribed in an effort to control healthcare costs and represent an increasing portion of the medicines used in the United States. The introduction of a generic drug as an alternative to a brand-name drug typically results in a dramatic reduction in the brand-name drug's market share, particularly within the first six months.

26. The Generic Pharmaceutical Association estimates that from 2001 through 2010, the nation's health care system saved \$931 billion from the use of generic drugs.

27. Before marketing a generic drug in the United States, a manufacturer must submit an ANDA to FDA, and FDA must approve it.

28. An ANDA applicant must show that its generic drug is as safe and effective as the approved brand-name drug, known as the "reference listed drug" or "RLD," in part by

demonstrating that the generic drug is bioequivalent to the RLD. 21 U.S.C. § 355(j)(2)(A). The two drug products are considered bioequivalent if the rate and extent of absorption of the generic drug does not differ significantly from the rate and extent of absorption of the brand-name drug. FDA has established regulations and scientific guidance on how an applicant can demonstrate bioequivalence.

29. Under Hatch-Waxman, brand companies are required to submit patents claiming an approved drug to FDA for inclusion in the agency's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

30. A generic drug manufacturer is free to perform bioequivalence testing and other research and drug development activities without fear of infringing the patents claiming the RLD that are listed in the Orange Book. The Patent Code expressly states that such research activities shall not constitute an act of infringement. 35 U.S.C. § 271(e)(1).

31. No generic manufacturer may file an ANDA seeking approval for a generic version of Ampyra® until January 22, 2014.

32. In order to be able to file an ANDA on January 22, 2014, Accord Healthcare must receive samples of the RLD immediately.

Risk Evaluation and Mitigation Strategies

33. The FDA lists Acorda as the holder of NDA No. 022250 for dalfampridine tablets, which Acorda markets as Ampyra®. FDA approved NDA No. 022250 on January 22, 2010, and Acorda began marketing Ampyra® in 2010.

34. Under the Food and Drug Administration Amendments Act of 2007, FDA has the authority to require Risk Evaluation and Mitigation Strategies ("REMS") from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. A REMS can include a medication guide, a patient package insert and potential restrictions on the distribution

of the drug (*e.g.*, by requiring practitioners, pharmacies or healthcare settings to obtain special certifications in order to dispense the drug). The REMS in place for Ampyra® simply requires that prescribers be advised of the potential risks associated with the use of Ampyra®.

35. In enacting the REMS framework, Congress anticipated that brand-name drug manufacturers like Acorda would use REMS programs as a basis for withholding samples of brand-name drugs from generic drug manufacturers like Accord Healthcare.

36. Accordingly, Congress enacted section 505-1(f)(8) of the FDCA (21 U.S.C. § 355-1(f)(8)) which prohibits a brand-name drug manufacturer from using a REMS "to block or delay approval of" an ANDA.

37. The FDA has stated publicly that REMS programs should not be used to block or delay generic competition.

38. The actions of Acorda and its agent or distributor H.D. Smith are in direct and intentional violation of this law.

FACTUAL BACKGROUND

Dalfampridine

39. Ampyra® is the brand-name drug containing the active ingredient dalfampridine.

40. Dalfampridine is a potassium channel blocker, and it works by improving the conduction of impulses between nerves of the central nervous system.

41. Ampyra® was approved by the FDA in 2010 to improve walking in patients with multiple sclerosis and was the first oral treatment approved by FDA for such treatment. Currently, there is no generic alternative for Ampyra®.

42. Ampyra® is subject to a REMS, based on the Ampyra® Access Program that was adopted in January 2010, at the time Ampyra® was approved by FDA. The REMS has subsequently been modified in July of 2012.

43. Ampyra® is extremely expensive, with an average yearly wholesale price of approximately \$10,000. Because of Acorda's monopoly power in this market, it has been able to maintain this premium pricing for Ampyra® since its inception.

44. Ampyra® has been an important product for the business of Acorda. Sales of Ampyra® have accounted for a large majority of the company's revenues. Upon information and belief, in 2012, Acorda's combined sales of Ampyra® were approximately \$266.1 million.

45. At least one analyst has noted that additional approved uses for Ampyra® could potentially double the company's sales. Acorda therefore has a pronounced incentive to maintain its monopoly over dalfampridine.

Accord Healthcare

46. As part of its normal research into promising candidates for generic drugs, Accord Healthcare identified the opportunity and need for a generic equivalent to Acorda's RLD Ampyra®.

47. Accord Healthcare is in the process of developing a generic product that it believes is bioequivalent to Ampyra®.

48. Before marketing the drug in the United States, Accord Healthcare must submit, and obtain approval by the FDA of, an ANDA.

49. The earliest date that any generic company may file an ANDA, because of statutory exclusivities in place, is January 22, 2014.

50. In order to be able to have its ANDA prepared for submission by January 22, 2014, Accord Healthcare must conduct bioequivalence testing, which requires that a clinical study begin in May, 2013, and that samples of the RLD are obtained immediately.

51. Before submitting an ANDA, Accord Healthcare must perform sufficient testing to demonstrate the bioequivalence between its generic product and Acorda's Ampyra®. To demonstrate bioequivalence, Accord Healthcare must obtain a sufficient quantity of Ampyra® to perform its bioequivalence testing.

52. If samples are not obtained in time to begin the necessary clinical trials the central commercial incentive for preparing and filing an ANDA, the ability of Accord Healthcare to file an ANDA for approval of its generic product will be eviscerated.

53. Ampyra® is therefore an essential facility, access to which is wholly controlled by Acorda.

Accord Healthcare Attempts to Purchase Ampyra® for Bioequivalence Testing

54. Accord Healthcare attempted to purchase samples of Ampyra® through normal wholesale distribution channels but was unable to do so.

55. Acorda has entered into agreements with the distributors of Ampyra® that, upon information and belief, prevents such distributors from supplying Ampyra® samples to Accord Healthcare and other generic manufacturers.

56. On March 20, 2013, Accord Healthcare sent Acorda and H.D. Smith, a letter seeking to purchase Ampyra® samples for bioequivalence testing. See Exhibit A.

57. In this letter, Accord Healthcare noted the quantity and amounts of Ampyra® that it sought to purchase and explained the following with respect to its request:

- a. The samples “of the RLD product are needed for conducting bioequivalence studies, for dissolution studies, and for product development purposes.”

- b. Accord Healthcare assured Acorda and its distributor H.D. Smith that “we will follow procedures that fully comply with the FDA requirements for conducting any required testing.”
- c. Accord Healthcare stated that the REMS requirement for Ampyra® should not be used as a basis for denying another drug manufacturer access to the drug for the purpose of conducting analytical and bioequivalence testing.
- d. Accord Healthcare further reiterated that it was willing “to pay Acorda Therapeutics, Inc. for the fair market value of the requested products and to reimburse for all reasonable shipping, handling and other costs associated with this purchase request,”

58. On March 20, 2013, Acorda’s agent, H.D. Smith, in Pompano Beach, Florida, responded by asking “[w]ho are your customers and what country would this product be used/dispensed in?”

59. In response, Accord Healthcare’s Director of Regulatory Affairs advised that the product was intended to be used in the United States.

60. Later on the same day, Accord Healthcare’s Director of Regulatory Affairs was asked if “you are a distributor?” and “[w]ho are your customers?” Accord Healthcare’s response was that “[w]e are a pharmaceutical company,” and “[w]e intend to use the samples for testing purposes,” and “[w]e will not be distributing the samples to any third parties.”

61. H.D Smith, as an authorized agent and distributor for Acorda refused to provide or sell the requested samples and responded that “[w]e are not interested.”

62. Acorda responded to the March 20, 2013 letter, and has refused to provide the samples. See Exhibit B.

63. Acorda's refusal to sell samples of Ampyra® to Accord Healthcare has caused significant and continuing delay in Accord Healthcare's preparations to file an ANDA for a generic dalfampridine product.

64. Acorda and H.D. Smith's refusal to sell the requested samples is not supported by any legitimate business justification.

65. But for Acorda's continuing refusal to sell such samples, Accord Healthcare would be able to perform the necessary testing in order to file an ANDA for approval of a generic dalfampridine product.

66. If Acorda continues to refuse to sell such samples, Accord Healthcare will be prevented from being in a position to obtain approval of that ANDA, at a minimum, before the new chemical exclusivity for the '826 Patent expires, or before other statutory exclusivities expire.

COUNT I
(Violation of Section 2 of The Sherman Act — Unlawful Monopolization)

67. Accord Healthcare realleges and incorporates by reference paragraphs 1 through 66 as if set forth in full.

68. The relevant market for Ampyra® is the market for dalfampridine in the United States. This market is characterized by significant entry barriers.

69. Acorda possesses monopoly power in the relevant market for Ampyra®. Acorda controls 100% of the commercial market for dalfampridine.

70. By refusing to sell samples of Ampyra® at market prices to Accord Healthcare so that Accord Healthcare can perform the bioequivalence testing necessary to submit an ANDA for generic dalfampridine, Acorda, either directly or through its agents, has unlawfully and willfully maintained its monopoly power in the relevant market, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

71. Acorda's refusal to sell samples of Ampyra® at market prices to Accord Healthcare for bioequivalence testing is intended to, and will, thwart the entry to market of any competing products, thereby extending its monopoly power in the relevant market.

72. Acorda does not have a legitimate, pro-competitive business purpose for refusing to sell samples of Ampyra® at market prices to Accord Healthcare.

73. Acorda's refusal to sell Accord Healthcare samples of Ampyra® at market prices, in furtherance of its unlawful monopoly, has the effect of delaying the testing that must be conducted by Accord Healthcare to prepare its ANDA with sufficient time for this drug.

74. Acorda's refusal to sell Accord Healthcare samples of Ampyra® will also have the effect of delaying the entry of a generic competitor, during which time:

- a. Competition in the manufacture, sale and distribution of dalfampridine is restrained, suppressed and eliminated;
- b. Acorda has sold and will continue to sell Ampyra® at artificially high, noncompetitive prices, reaping monopolist's profits in an amount to be determined at trial; and
- c. Deprived of the benefits of free and open competition in the purchase of dalfampridine, patients who purchase Ampyra® have been and will continue to be forced to pay artificially high, monopolist's prices for dalfampridine.

75. As a result of Acorda and H.D. Smith's unlawful conduct, Accord Healthcare has been injured in its business and property, in that Acorda's refusal to sell Accord Healthcare samples of Ampyra® has prevented and delayed Accord Healthcare from preparing its ANDA, and bringing a competing generic dalfampridine product to market, causing Accord Healthcare irreparable harm.

COUNT II
(Violation of Section 2 of The Sherman Act — Essential Facilities)

76. Accord Healthcare realleges and incorporates by reference paragraphs 1 through 75 as if set forth in full.

77. The relevant market for Ampyra® is the market for dalfampridine in the United States. This market is characterized by significant entry barriers.

78. It is impossible for a generic manufacturer like Accord Healthcare to bring a competing dalfampridine product to market without access to Ampyra® for bioequivalence testing. Ampyra®, the distribution of which is controlled by Acorda, is thus an essential facility for the production of generic dalfampridine, and Acorda is a monopolist with control over this essential facility.

79. By refusing to sell samples of Ampyra® at market prices to Accord Healthcare so that Accord Healthcare can perform the bioequivalence testing necessary to submit an ANDA for generic dalfampridine, Acorda has controlled an essential facility necessary for the production of dalfampridine, thereby effectively maintaining its monopoly power in the relevant market, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

80. Acorda's refusal to sell samples of Ampyra® at market prices to Accord Healthcare for bioequivalence testing is intended to and will extend its monopoly in the relevant market.

81. Accord Healthcare cannot practically or reasonably duplicate samples of Ampyra® for the purpose of conducting a bioequivalence study that satisfies FDA's requirements. In addition, Accord Healthcare cannot obtain samples of the FDA-approved version of Ampyra® from other sources, such as Acorda's wholesalers and distributors.

82. It would be feasible for Acorda to sell Accord Healthcare samples of Ampyra®. Acorda could simply sell Accord Healthcare the samples at full market prices, which Accord Healthcare has offered to pay. In attempting to purchase samples of Ampyra®, Accord Healthcare has assured Acorda that the samples would not be sold to any patient in the United States, and that all reasonably necessary controls for the access and handling of the samples under the REMS would be implemented.

83. Acorda does not have a legitimate, pro-competitive business purpose for refusing to sell Accord Healthcare samples of Ampyra® at market prices.

84. Acorda's refusal to sell Accord Healthcare samples of Ampyra® at market prices, in furtherance of its unlawful monopoly, will have the effect of delaying the entry of a generic competitor for many months, during which time:

- a. Competition in the manufacture, sale and distribution of dalfampridine is restrained, suppressed and eliminated;
- b. Acorda has sold and will continue to sell Ampyra® at artificially high, noncompetitive prices, reaping monopolist's profits in an amount to be determined at trial; and
- c. Deprived of the benefits of free and open competition in the purchase of dalfampridine, patients who purchase Ampyra® have been and will continue to be forced to pay artificially high, monopolist's prices for dalfampridine.

85. As a result of Acorda's unlawful conduct, Accord Healthcare has been injured in its business and property, in that Acorda's refusal to sell Accord Healthcare samples of Ampyra® has prevented and delayed Accord Healthcare from bringing a competing generic dalfampridine product to market, causing Accord Healthcare damages in an amount to be determined at trial.

COUNT III
(Violation of The Florida Antitrust Act — Unlawful Monopolization)

86. Accord Healthcare realleges and incorporates by reference paragraphs 1 through 85 as if set forth in full.

87. The relevant market for purposes of The Florida Antitrust Act is the market for dalfampridine in Florida. This market is characterized by significant entry barriers.

88. Acorda possesses monopoly power in the relevant market, controlling 100% of the commercial market for dalfampridine in Florida.

89. By refusing to sell samples of Ampyra® at market prices to Accord Healthcare so that Accord Healthcare can perform the bioequivalence testing necessary to submit an ANDA for generic dalfampridine, Acorda has unlawfully and willfully maintained its monopoly power in the relevant market, in violation of The Florida Antitrust Act, Fla. Stat. Section 542.19.

90. Acorda's refusal to sell samples of Ampyra® at market prices to Accord Healthcare, in furtherance of its unlawful monopoly, will have the effect of delaying the entry of a generic competitor for many months, during which time:

- a. Competition in the manufacture, sale and distribution of dalfampridine in Florida is restrained, suppressed and eliminated;
- b. Acorda has sold and will continue to sell Ampyra® in Florida at artificially high, noncompetitive prices, reaping monopolist's profits in an amount to be determined at trial; and
- c. Deprived of the benefits of free and open competition in the purchase of dalfampridine, patients who purchase Ampyra® in Florida have been and will continue to be forced to pay artificially high, monopolist's prices for dalfampridine.

91. As a result of Acorda's unlawful conduct, Accord Healthcare has been injured in its business and property, in that Acorda's refusal to sell Accord Healthcare samples of Ampyra®

has prevented and delayed Accord Healthcare from bringing a competing generic dalfampridine product to market, causing Accord Healthcare damages in an amount to be determined at trial.

**COUNT IV
(Violation of The Florida Antitrust Act — Essential Facilities)**

92. Accord Healthcare realleges and incorporates by reference paragraphs 1 through 91 as if set forth in full.

93. The relevant market for purposes of The Florida Antitrust Act is the market for dalfampridine in Florida. This market is characterized by significant entry barriers.

94. Acorda possesses monopoly power in the relevant market, controlling 100% of the commercial market for dalfampridine in Florida.

95. By refusing to sell Accord Healthcare samples of Ampyra® at market prices so that Accord Healthcare can perform the bioequivalence testing necessary to submit an ANDA for generic dalfampridine Acorda has controlled an essential facility necessary for the production of dalfampridine, thereby effectively maintaining its monopoly power in the relevant market, in violation of The Florida Antitrust Act, Fla. Stat. § 542.19.

96. Acorda's refusal to sell Accord Healthcare samples of Ampyra® at market prices, in furtherance of its unlawful monopoly, will have the effect of delaying the entry of a generic competitor for many months, during which time:

- a. Competition in the manufacture, sale and distribution of dalfampridine in Florida is restrained, suppressed and eliminated;
- b. Acorda has sold and will continue to sell Ampyra® in Florida at artificially high, noncompetitive prices, reaping monopolist's profits in an amount to be determined at trial; and

- c. Deprived of the benefits of free and open competition in the purchase of Ampyra®, patients who purchase Ampyra® in Florida have been and will continue to be forced to pay artificially high, monopolist's prices for dalfampridine.

97. As a result of Acorda's unlawful conduct, Accord Healthcare has been injured in its business and property, in that Acorda's refusal to sell Accord Healthcare samples of Ampyra® has prevented and delayed Accord Healthcare from bringing a generic dalfampridine product to market, causing Accord Healthcare damages in an amount to be determined at trial.

COUNT V
(Tortious Interference with a Prospective Business Relationship)

98. Accord Healthcare realleges and incorporates by reference paragraphs 1 through 97 as if set forth in full.

99. Accord Healthcare has a reasonable expectation of economic advantage from a prospective economic relationship with individuals currently suffering from multiple sclerosis, to whom it would sell a generic dalfampridine product.

100. Acorda is aware of Accord Healthcare's intention to submit an ANDA for a generic dalfampridine product.

101. Accordingly, Acorda is aware of Accord Healthcare's reasonable expectation of economic advantage from the FDA's review and approval of its anticipated ANDA application, and (if approved) the eventual sales of a generic dalfampridine product.

102. By refusing to sell Accord Healthcare samples of Ampyra® at market prices so that Accord Healthcare can perform the bioequivalence testing necessary to submit an ANDA for generic dalfampridine, Acorda has intentionally and maliciously interfered with Accord Healthcare's reasonable expectation of economic advantage from sales of a generic

dalfampridine product. Acorda does not have a legitimate, pro-competitive business purpose for refusing to sell Accord Healthcare samples of Ampyra® at market prices.

103. In the absence of Acorda's refusal to sell Accord Healthcare samples of Ampyra®, there is a reasonable probability that Accord Healthcare would be able to sell a generic dalfampridine product to individuals suffering from multiple sclerosis and would realize an economic benefit from such sales.

104. Acorda's tortious interference has directly and proximately caused injury to Accord Healthcare's business and property, including but not limited to lost profits and lost business opportunities.

**COUNT VI
(Mandatory Injunctive Relief)**

105. Accord Healthcare realleges and incorporates by reference paragraphs 1 through 104 as if set forth in full.

106. Accord Healthcare has a reasonable probability of success on the merits.

107. Accord Healthcare's right to relief, in the form of timely access to sufficient samples of Ampyra® to enable it to perform bioequivalence testing in support of an ANDA, is clear.

108. As a result of Acorda's unlawful conduct, as alleged herein, Accord Healthcare will continue to suffer immediate and irreparable harm that cannot be fully remedied by money damages.

109. Accord Healthcare does not have an adequate remedy at law.

110. Granting immediate injunctive relief to Accord Healthcare will not result in greater harm to Acorda.

111. Granting immediate injunctive relief to Accord Healthcare will be in the public interest, as it will finally allow the pursuit of lower-cost, generic competitors to an important drug used to treat a potentially fatal disease, resulting in competition in the relevant product and geographic markets.

112. Accord Healthcare is entitled to a mandatory and immediate injunction pursuant to 15 U.S.C. § 26 and Fed. R. Civ. P. 65, requiring Acorda to sell Accord Healthcare sufficient quantities of Ampyra® tablets at market prices so that Accord Healthcare can perform the bioequivalence testing necessary to support an ANDA for a generic dalfampridine product.

**COUNT VII
(Declaratory Relief)**

113. Accord Healthcare realleges and incorporates by reference paragraphs 1 through 112 above as if set forth in full.

114. Accord Healthcare seeks to submit an ANDA to manufacture generic dalfampridine. The OGD has stated that this ANDA must demonstrate bioequivalence based on bioequivalence studies performed using the RLD (*i.e.*, FDA-approved) Ampyra®.

115. Accord Healthcare has requested that Acorda sell Accord Healthcare sufficient samples of Ampyra® to perform this bioequivalence testing, and has indicated that it will pay Acorda market price for these samples and will take all reasonably necessary and appropriate precautions in handling the drug.

116. Nevertheless, Acorda has refused to sell samples of Ampyra® to Accord Healthcare and has claimed that it has no obligation to sell Ampyra® to Accord Healthcare.

117. Thus, a dispute currently exists between Acorda and Accord Healthcare with respect to Acorda's obligation to sell Accord Healthcare samples of Ampyra® for bioequivalence testing.

118. Accord Healthcare is therefore entitled, pursuant to the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, to a declaration of rights and obligations whereby Acorda is obliged to sell Accord Healthcare sufficient quantities of Ampyra® at market prices so that Accord Healthcare can perform the bioequivalence testing necessary to support an ANDA for a generic dalfampridine product.

PRAYER FOR RELIEF

WHEREFORE, Accord Healthcare respectfully requests judgment in its favor and against Acorda as follows:

- a. Granting preliminary and permanent mandatory injunctive relief pursuant to 15 U.S.C. § 26, Fed. R. Civ. P. 65, and Florida Statute § 542.23 compelling Acorda to immediately sell Accord Healthcare sufficient quantities of Ampyra® at market prices so that Accord Healthcare can perform bioequivalence testing;
- b. Treble damages pursuant to 15 U.S.C. § 15 and Florida Statute § 542.22;
- c. An award of attorneys' fees and costs pursuant to 28 U.S.C. § 15 and Florida Statute § 542.22;
- d. A declaration that Acorda is required to sell Accord Healthcare sufficient samples of Ampyra® so that Accord Healthcare can perform bioequivalence testing; and
- e. Such other and further relief as the Court deems just and proper.

Date: April 1, 2013

SIGNATURE ON PAGE 21

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