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Jazz Pharmaceuticals Ireland Limited*

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

**JAZZ PHARMACEUTICALS, INC. and
JAZZ PHARMACEUTICALS IRELAND
LIMITED,**

Plaintiffs,

v.

ASCENT PHARMACEUTICALS, INC.,

Defendant.

Civil Action No. _____

**COMPLAINT
FOR PATENT INFRINGEMENT**

(Filed Electronically)

Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, “Jazz Pharmaceuticals” or “Plaintiffs”), by their undersigned attorneys, for their Complaint against Defendant, Ascent Pharmaceuticals, Inc. (“Ascent” or “Defendant”), allege as follows:

Nature of the Action

1. This action is for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Ascent’s filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market a generic version of Jazz Pharmaceuticals’ XYREM[®] drug product prior to the expiration of United States Patent Nos. 6,472,431 (the “431 patent”), 6,780,889 (the “889

patent”), 7,262,219 (the “219 patent”), 7,851,506 (the “506 patent”), 8,263,650 (the “650 patent”), 8,324,275 (the “275 patent”), 8,461,203 (the “203 patent”), 7,668,730 (the “730 patent”), 7,765,106 (the “106 patent”), 7,765,107 (the “107 patent”), 7,895,059 (the “059 patent”), 8,457,988 (the “988 patent”), 8,589,182 (the “182 patent”), 8,731,963 (the “963 patent”), 8,772,306 (the “306 patent”), 8,859,619 (the “619 patent”), 8,952,062 (the “062 patent”), 9,539,330 (the “330 patent”), 9,486,426 (the “426 patent”), and 9,050,302 (the “302 patent”) owned by Jazz Pharmaceuticals (collectively, “the patents-in-suit”).

The Parties

2. Plaintiff Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3180 Porter Drive, Palo Alto, California 94304.

3. Plaintiff Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, having a principal place of business at Waterloo Exchange, Waterloo Road, Dublin, Ireland 4.

4. On information and belief, Defendant Ascent is a New York corporation organized and existing under the laws of the State of New York, having its principal place of business at 550 S. Research Pl, Central Islip, NY 11722, and its registered office at 550 S. Research Pl, Central Islip, NY 11722.

5. Ascent is registered to do business in New York under DOS ID #: 4136894. On information and belief, Ascent is in the business of, *inter alia*, developing, manufacturing, distributing, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its affiliates. On information and belief, Ascent holds itself out as a single entity for the purposes of the manufacture, sale, marketing, distribution, and importation of generic drug products.

6. On information and belief, following any FDA approval of ANDA No. 210523, Ascent will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 210523 throughout the United States, and/or import such generic products into the United States.

Jurisdiction and Venue

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. On information and belief, Ascent is subject to personal jurisdiction in New York because of its systematic and continuous contacts with the State of New York. On information and belief, Ascent is registered to do business in New York (DOS ID#: 4136894), and has and/or will either directly or indirectly, develop, manufacture, distribute, market, offer to sell, and sell generic products for sale and use throughout the United States, including within this Judicial District.

9. Because Ascent is headquartered and/or registered to do business in New York, it is subject to general personal jurisdiction in this Judicial District.

10. On information and belief, Ascent is subject to personal jurisdiction in New York because, among other things, Ascent has purposely availed itself of the benefits and protections of New York's laws such that it should reasonably anticipate being haled into court in New York. On information and belief, Ascent has and/or will manufacture, market, and/or sell generic drugs throughout the United States and within the State of New York and therefore transact business within the State of New York related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New York.

11. On information and belief, by virtue of, *inter alia*, Ascent's continuous and systematic contacts with New York, including but not limited to the above-described contacts,

and the actions on behalf of Ascent in connection with ANDA No. 210523, this Court has personal jurisdiction over Ascent. These activities satisfy due process and confer personal jurisdiction over Ascent consistent with New York law.

12. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents-In-Suit

13. On October 29, 2002, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’431 patent, entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy.” A copy of the ’431 patent is attached hereto as Exhibit A.

14. On August 24, 2004, the USPTO duly and lawfully issued the ’889 patent, entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy.” A copy of the ’889 patent is attached hereto as Exhibit B.

15. On August 28, 2007, the USPTO duly and lawfully issued the ’219 patent, entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy.” A copy of the ’219 patent is attached hereto as Exhibit C.

16. On December 14, 2010, the USPTO duly and lawfully issued the ’506 patent, entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy.” A copy of the ’506 patent is attached hereto as Exhibit D.

17. On September 11, 2012, the USPTO duly and lawfully issued the ’650 patent, entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy.” A copy of the ’650 patent is attached hereto as Exhibit E.

18. On December 4, 2012, the USPTO duly and lawfully issued the ’275 patent, entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy.” A copy of the ’275 patent is attached hereto as Exhibit F.

19. On June 11, 2013, the USPTO duly and lawfully issued the '203 Patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '203 patent is attached hereto as Exhibit G.

20. On February 23, 2010, the USPTO duly and lawfully issued the '730 patent, entitled "Sensitive Drug Distribution System and Method." A copy of the '730 patent is attached hereto as Exhibit H.

21. On July 27, 2010, the USPTO duly and lawfully issued the '106 patent, entitled "Sensitive Drug Distribution System and Method." A copy of the '106 patent is attached hereto as Exhibit I.

22. On July 27, 2010, the USPTO duly and lawfully issued the '107 patent, entitled "Sensitive Drug Distribution System and Method." A copy of the '107 patent is attached hereto as Exhibit J.

23. On February 22, 2011, the USPTO duly and lawfully issued the '059 patent, entitled "Sensitive Drug Distribution System and Method." A copy of the '059 patent is attached hereto as Exhibit K.

24. On June 4, 2013, the USPTO duly and lawfully issued the '988 patent, entitled "Sensitive Drug Distribution System and Method." A copy of the '988 patent is attached hereto as Exhibit L.

25. On November 19, 2013, the USPTO duly and lawfully issued the '182 patent, entitled "Sensitive Drug Distribution System and Method." A copy of the '182 patent is attached hereto as Exhibit M.

26. On May 20, 2014, the USPTO duly and lawfully issued the '963 patent, entitled "Sensitive Drug Distribution System and Method." A copy of the '963 patent is attached hereto as Exhibit N.

27. On July 8, 2014, the USPTO duly and lawfully issued the '306 patent, entitled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters." A copy of the '306 patent is attached hereto as Exhibit O.

28. On October 14, 2014, the USPTO duly and lawfully issued the '619 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '619 patent is attached hereto as Exhibit P.

29. On February 10, 2015, the USPTO duly and lawfully issued the '062 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '062 patent is attached hereto as Exhibit Q.

30. On June 9, 2015, the USPTO duly and lawfully issued the '302 patent, entitled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters." A copy of the '302 patent is attached hereto as Exhibit R.

31. On November 8, 2016, the USPTO duly and lawfully issued the '426 patent, entitled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters." A copy of the '426 patent is attached hereto as Exhibit S.

32. On January 10, 2017, the USPTO duly and lawfully issued the '330 patent, entitled, "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '330 patent is attached hereto as Exhibit T.

The XYREM[®] Drug Product

33. Jazz Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for

sodium oxybate oral solution (NDA No. 21-196), which it sells under the trade name XYREM[®]. The claims of the patents-in-suit cover, *inter alia*, pharmaceutical compositions containing sodium oxybate, and methods of use and administration of sodium oxybate or pharmaceutical compositions containing sodium oxybate. Jazz Pharmaceuticals owns the patents-in-suit.

34. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, '963, '306, '619, '062, '330, '426, and '302 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to XYREM[®].

35. The labeling for XYREM[®] instructs and encourages physicians, other healthcare workers, and patients to administer XYREM[®] according to the methods claimed in several of the patents-in-suit.

Acts Giving Rise to This Suit

36. Pursuant to Section 505 of the FFDCFA, Ascent filed ANDA No. 210523 ("Ascent's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of 500 mg/mL sodium oxybate oral solution ("Ascent's Proposed Product"), before the patents-in-suit expire.

37. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Ascent has provided a written certification to the FDA, as called for by Section 505 of the FFDCFA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Ascent's Paragraph IV Certification"), alleging that the claims of the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, '963, '306, '619, '062, '330, '426 and '302 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Ascent's ANDA.

38. No earlier than June 14, 2017, Jazz Pharmaceuticals received written notice of Ascent's Paragraph IV Certification ("Ascent's Notice Letter") pursuant to

21 U.S.C. § 355(j)(2)(B). Ascent's Notice Letter alleged that the claims of the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, '963, '306, '619, '062, '330, '426 and '302 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Ascent's ANDA. Ascent's Notice Letter also informed Jazz Pharmaceuticals that Ascent seeks approval to market Ascent's Proposed Product before the patents-in-suit expire.

39. On information and belief, Ascent has not submitted a statement to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) that Ascent seeks to market its Proposed Product for a use other than the uses claimed in the patents-in-suit.

40. Under applicable laws and regulations, the FDA will not approve Ascent's Proposed Product with labeling that does not include information regarding dose modification in patients receiving concomitant administration of sodium oxybate and valproate that is necessary for the safe and effective use of sodium oxybate.

Count I: Infringement of the '431 Patent

41. Plaintiffs repeat and reallege the allegations of paragraphs 1-40 as though fully set forth herein.

42. Ascent, through its submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '431 patent. Ascent's actions with respect to its ANDA show that there is a substantial controversy, between the parties, of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

43. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution prior to the

expiration of the '431 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

44. There is a justiciable controversy between the parties hereto as to the infringement of the '431 patent.

45. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '431 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

46. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '431 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '431 patent and knowledge that its acts are encouraging infringement.

47. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '431 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '431 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

48. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '431 patent is not enjoined.

49. Jazz Pharmaceuticals does not have an adequate remedy at law.

50. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '889 Patent

51. Plaintiffs repeat and reallege the allegations of paragraphs 1-50 as though fully set forth herein.

52. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '889 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

53. There is a justiciable controversy between the parties hereto as to the infringement of the '889 patent.

54. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '889 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

55. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '889 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '889 patent and knowledge that its acts are encouraging infringement.

56. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '889 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's

Proposed Product is especially adapted for a use that infringes the '889 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

57. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '889 patent is not enjoined.

58. Jazz Pharmaceuticals does not have an adequate remedy at law.

59. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '219 Patent

60. Plaintiffs repeat and reallege the allegations of paragraphs 1-59 as though fully set forth herein.

61. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '219 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

62. There is a justiciable controversy between the parties hereto as to the infringement of the '219 patent.

63. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '219 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

64. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '219 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally

encourage acts of direct infringement with knowledge of the '219 patent and knowledge that its acts are encouraging infringement.

65. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '219 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '219 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

66. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '219 patent is not enjoined.

67. Jazz Pharmaceuticals does not have an adequate remedy at law.

68. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '506 Patent

69. Plaintiffs repeat and reallege the allegations of paragraphs 1-68 as though fully set forth herein.

70. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '506 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

71. There is a justiciable controversy between the parties hereto as to the infringement of the '506 patent.

72. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '506 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

73. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '506 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '506 patent and knowledge that its acts are encouraging infringement.

74. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '506 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '506 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

75. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '506 patent is not enjoined.

76. Jazz Pharmaceuticals does not have an adequate remedy at law.

77. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count V: Infringement of the '650 Patent

78. Plaintiffs repeat and reallege the allegations of paragraphs 1-77 as though fully set forth herein.

79. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '650 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

80. There is a justiciable controversy between the parties hereto as to the infringement of the '650 patent.

81. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '650 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

82. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '650 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '650 patent and knowledge that its acts are encouraging infringement.

83. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily the claims of infringe the '650 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '650 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

84. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '650 patent is not enjoined.

85. Jazz Pharmaceuticals does not have an adequate remedy at law.

86. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI: Infringement of the '275 Patent

87. Plaintiffs repeat and reallege the allegations of paragraphs 1-86 as though fully set forth herein.

88. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '275 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

89. There is a justiciable controversy between the parties hereto as to the infringement of the '275 patent.

90. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '275 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

91. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '275 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '275 patent and knowledge that its acts are encouraging infringement.

92. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '275 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '275 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

93. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '275 patent is not enjoined.

94. Jazz Pharmaceuticals does not have an adequate remedy at law.

95. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VII: Infringement of the '203 Patent

96. Plaintiffs repeat and reallege the allegations of paragraphs 1-95 as though fully set forth herein.

97. Ascent, through its submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '203 patent. Ascent's actions with respect to its ANDA show that there is a substantial controversy, between the parties, of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

98. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution prior to the expiration of the '203 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

99. There is a justiciable controversy between the parties hereto as to the infringement of the '203 patent.

100. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '203 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

101. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '203 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '203 patent and knowledge that its acts are encouraging infringement.

102. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '203 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '203 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

103. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '203 patent is not enjoined.

104. Jazz Pharmaceuticals does not have an adequate remedy at law.

105. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VIII: Infringement of the '730 Patent

106. Plaintiffs repeat and reallege the allegations of paragraphs 1-105 as though fully set forth herein.

107. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '730 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

108. There is a justiciable controversy between the parties hereto as to the infringement of the '730 patent.

109. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '730 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

110. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '730 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '730 patent and knowledge that its acts are encouraging infringement.

111. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '730 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '730 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

112. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '730 patent is not enjoined.

113. Jazz Pharmaceuticals does not have an adequate remedy at law.

114. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IX: Infringement of the '106 Patent

115. Plaintiffs repeat and reallege the allegations of paragraphs 1-114 as though fully set forth herein.

116. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '106 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

117. There is a justiciable controversy between the parties hereto as to the infringement of the '106 patent.

118. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '106 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

119. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '106 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '106 patent and knowledge that its acts are encouraging infringement.

120. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '106 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '106 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

121. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '106 patent is not enjoined.

122. Jazz Pharmaceuticals does not have an adequate remedy at law.

123. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count X: Infringement of the '107 Patent

124. Plaintiffs repeat and reallege the allegations of paragraphs 1-123 as though fully set forth herein.

125. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '107 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

126. There is a justiciable controversy between the parties hereto as to the infringement of the '107 patent.

127. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '107 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

128. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '107 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally

encourage acts of direct infringement with knowledge of the '107 patent and knowledge that its acts are encouraging infringement.

129. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '107 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '107 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

130. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '107 patent is not enjoined.

131. Jazz Pharmaceuticals does not have an adequate remedy at law.

132. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XI: Infringement of the '059 Patent

133. Plaintiffs repeat and reallege the allegations of paragraphs 1-132 as though fully set forth herein.

134. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '059 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

135. There is a justiciable controversy between the parties hereto as to the infringement of the '059 patent.

136. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '059 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

137. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '059 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '059 patent and knowledge that its acts are encouraging infringement.

138. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '059 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '059 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

139. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '059 patent is not enjoined.

140. Jazz Pharmaceuticals does not have an adequate remedy at law.

141. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XII: Infringement of the '988 Patent

142. Plaintiffs repeat and reallege the allegations of paragraphs 1-141 as though fully set forth herein.

143. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '988 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

144. There is a justiciable controversy between the parties hereto as to the infringement of the '988 patent.

145. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '988 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

146. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '988 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '988 patent and knowledge that its acts are encouraging infringement.

147. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '988 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '988 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

148. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '988 patent is not enjoined.

149. Jazz Pharmaceuticals does not have an adequate remedy at law.

150. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XIII: Infringement of the '182 Patent

151. Plaintiffs repeat and reallege the allegations of paragraphs 1-150 as though fully set forth herein.

152. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '182 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

153. There is a justiciable controversy between the parties hereto as to the infringement of the '182 patent.

154. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '182 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

155. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '182 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '182 patent and knowledge that its acts are encouraging infringement.

156. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '182 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '182 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

157. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '182 patent is not enjoined.

158. Jazz Pharmaceuticals does not have an adequate remedy at law.

159. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XIV: Infringement of the '963 Patent

160. Plaintiffs repeat and reallege the allegations of paragraphs 1-159 as though fully set forth herein.

161. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '963 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

162. There is a justiciable controversy between the parties hereto as to the infringement of the '963 patent.

163. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '963 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

164. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '963 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally

encourage acts of direct infringement with knowledge of the '963 patent and knowledge that its acts are encouraging infringement.

165. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '963 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '963 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

166. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '963 patent is not enjoined.

167. Jazz Pharmaceuticals does not have an adequate remedy at law.

168. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XV: Infringement of the '306 Patent

169. Plaintiffs repeat and reallege the allegations of paragraphs 1-168 as though fully set forth herein.

170. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '306 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

171. There is a justiciable controversy between the parties hereto as to the infringement of the '306 patent.

172. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '306 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

173. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '306 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '306 patent and knowledge that its acts are encouraging infringement.

174. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '306 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '306 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

175. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '306 patent is not enjoined.

176. Jazz Pharmaceuticals does not have an adequate remedy at law.

177. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XVI: Infringement of the '619 Patent

178. Plaintiffs repeat and reallege the allegations of paragraphs 1-177 as though fully set forth herein.

179. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '619 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

180. There is a justiciable controversy between the parties hereto as to the infringement of the '619 patent.

181. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '619 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

182. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '619 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '619 patent and knowledge that its acts are encouraging infringement.

183. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '619 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '619 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

184. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '619 patent is not enjoined.

185. Jazz Pharmaceuticals does not have an adequate remedy at law.

186. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XVII: Infringement of the '062 Patent

187. Plaintiffs repeat and reallege the allegations of paragraphs 1-186 as though fully set forth herein.

188. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '062 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

189. There is a justiciable controversy between the parties hereto as to the infringement of the '062 patent.

190. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '062 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

191. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '062 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '062 patent and knowledge that its acts are encouraging infringement.

192. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '062 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '062 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

193. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '062 patent is not enjoined.

194. Jazz Pharmaceuticals does not have an adequate remedy at law.

195. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XVIII: Infringement of the '302 Patent

196. Plaintiffs repeat and reallege the allegations of paragraphs 1-195 as though fully set forth herein.

197. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '302 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

198. There is a justiciable controversy between the parties hereto as to the infringement of the '302 patent.

199. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '302 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

200. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '302 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally

encourage acts of direct infringement with knowledge of the '302 patent and knowledge that its acts are encouraging infringement.

201. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '302 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '302 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

202. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '302 patent is not enjoined.

203. Jazz Pharmaceuticals does not have an adequate remedy at law.

204. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XIX: Infringement of the '330 Patent

205. Plaintiffs repeat and reallege the allegations of paragraphs 1-204 as though fully set forth herein.

206. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '330 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

207. There is a justiciable controversy between the parties hereto as to the infringement of the '330 patent.

208. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '330 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

209. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '330 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '330 patent and knowledge that its acts are encouraging infringement.

210. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily the claims of infringe the '330 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '330 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

211. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '330 patent is not enjoined.

212. Jazz Pharmaceuticals does not have an adequate remedy at law.

213. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XX: Infringement of the '426 Patent

214. Plaintiffs repeat and reallege the allegations of paragraphs 1-213 as though fully set forth herein.

215. Ascent's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '426 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

216. There is a justiciable controversy between the parties hereto as to the infringement of the '426 patent.

217. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe the claims of the '426 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States.

218. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of the claims of the '426 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '426 patent and knowledge that its acts are encouraging infringement.

219. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe the claims of the '426 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Ascent's Proposed Product in the United States. On information and belief, Ascent has had and continues to have knowledge that Ascent's Proposed Product is especially adapted for a use that infringes the '426 patent and that there is no substantial non-infringing use for Ascent's Proposed Product.

220. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ascent's infringement of the '426 patent is not enjoined.

221. Jazz Pharmaceuticals does not have an adequate remedy at law.

222. This case is exceptional, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment be entered that Ascent has infringed the patents-in-suit by submitting ANDA No. 210523;

(B) A Judgment be entered that Ascent has infringed, and that Ascent's making, using, selling, offering to sell, or importing Ascent's Proposed Product will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 210523 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Ascent and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Ascent's Proposed Product until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Ascent, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any pharmaceutical compositions or methods as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Ascent's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Ascent has committed any acts with respect to the compositions and/or methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiffs be awarded damages for such acts;

(H) If Ascent engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Ascent's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(I) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: July 27, 2017

By: s/ Eric C. Stops

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