Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Jazz Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC., **Plaintiff,** **v.** **PAR PHARMACEUTICAL, INC.,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Jazz Pharmaceuticals, Inc. ("Jazz Pharmaceuticals"), by its undersigned attorneys, for its Complaint against defendant Par Pharmaceutical, Inc. ("Par"), alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Par'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"), and 8,589,182 (the "'182 patent") owned by Jazz Pharmaceuticals (collectively, "the patents-in-suit").

The Parties

2. Plaintiff Jazz Pharmaceuticals 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. On information and belief, defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey.

4. On information and belief, Par develops numerous generic drugs for sale and use throughout the United States, including in this judicial district. Par has litigated patent cases in this District in the past without contesting personal jurisdiction, and, in at least some of those actions, Par has asserted counterclaims.

Jurisdiction and Venue

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

6. This Court has personal jurisdiction over Par by virtue of, *inter alia,* its systematic and continuous contacts with the State of New Jersey. On information and belief, Par has its principal place of business in Woodcliff Lake, New Jersey, conducts business in this District, purposefully avails itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Also, on information and belief,

Par has customers in the State of New Jersey. Further, on information and belief, Par is registered to conduct business in the State of New Jersey.

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

The Patent-In-Suit

8. 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" to inventors Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. The '431 patent was later assigned to Jazz Pharmaceuticals. A copy of the '431 patent is attached hereto as Exhibit A.

9. 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" to inventors Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. The '889 patent was later assigned to Jazz Pharmaceuticals. A copy of the '889 patent is attached hereto as Exhibit B.

10. 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" to inventors Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. The '219 patent was later assigned to Jazz Pharmaceuticals. A copy of the '219 patent is attached hereto as Exhibit C.

11. 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" to Jazz Pharmaceuticals as assignee of the inventors Harry Cook,

Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. A copy of the '506 patent is attached hereto as Exhibit D.

12. 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" to Jazz Pharmaceuticals as assignee of the inventors Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. A copy of the '650 patent is attached hereto as Exhibit E.

13. 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" to Jazz Pharmaceuticals as assignee of the inventors Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. A copy of the '275 patent is attached hereto as Exhibit F.

14. 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" to Jazz Pharmaceuticals as assignee of the inventors Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. A copy of the '203 patent is attached hereto as Exhibit G.

15. On February 23, 2010, the USPTO duly and lawfully issued the '730 patent, entitled "Sensitive Drug Distribution System and Method" to inventors Dayton Reardan, Patti Engle and Bob Gagne. The '730 patent was later assigned to Jazz Pharmaceuticals. A copy of the '730 patent is attached hereto as Exhibit H.

16. On July 27, 2010, the USPTO duly and lawfully issued the '106 patent, entitled "Sensitive Drug Distribution System and Method" to inventors Dayton Reardan, Patti Engle and

Bob Gagne. The '106 patent was later assigned to Jazz Pharmaceuticals. A copy of the '106 patent is attached hereto as Exhibit I.

17. On July 27, 2010, the USPTO duly and lawfully issued the '107 patent, entitled "Sensitive Drug Distribution System and Method" to inventors Dayton Reardan, Patti Engle and Bob Gagne. The '107 patent was later assigned to Jazz Pharmaceuticals. A copy of the '107 patent is attached hereto as Exhibit J.

18. On February 22, 2011, the USPTO duly and lawfully issued the '059 patent, entitled "Sensitive Drug Distribution System and Method" to Jazz Pharmaceuticals as assignee of the inventors Dayton Reardan, Patti Engle and Bob Gagne. A copy of the '059 patent is attached hereto as Exhibit K.

19. On June 4, 2013, the USPTO duly and lawfully issued the '988 patent, entitled "Sensitive Drug Distribution System and Method" to Jazz Pharmaceuticals as assignee of the inventors Dayton Reardan, Patti Engle and Bob Gagne. A copy of the '988 patent is attached hereto as Exhibit L.

20. On November 19, 2013, the USPTO duly and lawfully issued the '182 patent, entitled "Sensitive Drug Distribution System and Method" to Jazz Pharmaceuticals as assignee of the inventors Dayton Reardan, Patti Engle and Bob Gagne. A copy of the '182 patent is attached hereto as Exhibit M.

The XYREM® Drug Product

21. 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.

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

Acts Giving Rise to This Suit

23. Pursuant to Section 505 of the FFDCA, Par filed ANDA No. 205403 ("Par'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 ("Par's Proposed Product"), before the patents-in-suit expire.

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

25. No earlier than November 20, 2013, Jazz Pharmaceuticals received written notice of Par's Paragraph IV Certification ("Par's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Par's Notice Letter alleged that the claims of the '889, '219, '506, '650, '275, '730, '106, '107, '059, and '988 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Par's ANDA. Par's Notice Letter also informed Jazz Pharmaceuticals that Par seeks approval to market Par's Proposed Product before the patents-in-suit expire.

Count I: Infringement of the '431 Patent

26. Plaintiff repeats and realleges the allegations of paragraphs 1-25 as though fully set forth herein.

27. Par, 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. Par's actions with respect to its ANDA show that there is a substantial controversy, between the parties, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

28. Par'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 of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

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

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

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

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

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

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

35. This case is an exceptional one, 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

36. Plaintiff repeats and realleges the allegations of paragraphs 1-35 as though fully set forth herein.

37. Par'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).

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

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

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

41. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will contributorily infringe the '889 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Par's Proposed Product in the United States. On information and belief, Par has had and continues to have knowledge that Par's Proposed Product is especially adapted for a use that infringes the '889 patent and that there is no substantial non-infringing use for Par's Proposed Product.

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

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

44. This case is an exceptional one, 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

45. Plaintiff repeats and realleges the allegations of paragraphs 1-44 as though fully set forth herein.

46. Par'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).

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

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

49. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will induce infringement of the '219 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Par's Proposed Product in the United States. On information and belief, upon FDA approval of Par's ANDA, Par will intentionally encourage acts of direct infringement with knowledge of the '219 patent and knowledge that its acts are encouraging infringement.

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

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

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

53. This case is an exceptional one, 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

54. Plaintiff repeats and realleges the allegations of paragraphs 1-53 as though fully set forth herein.

55. Par'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).

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

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

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

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

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

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

62. This case is an exceptional one, 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

63. Plaintiff repeats and realleges the allegations of paragraphs 1-62 as though fully set forth herein.

64. Par'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).

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

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

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

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

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

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

71. This case is an exceptional one, 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

72. Plaintiff repeats and realleges the allegations of paragraphs 1-71 as though fully set forth herein.

73. Par'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).

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

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

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

77. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will contributorily infringe the '275 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Par's Proposed Product in the United States. On information and belief, Par has had and continues to have knowledge that Par's Proposed Product is especially adapted for a use that infringes the '275 patent and that there is no substantial non-infringing use for Par's Proposed Product.

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

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

80. This case is an exceptional one, 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

81. Plaintiff repeats and realleges the allegations of paragraphs 1-80 as though fully set forth herein.

82. Par, 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. Par's actions with respect to its ANDA show that there is a substantial controversy,

between the parties, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

83. Par'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 of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

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

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

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

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

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

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

90. This case is an exceptional one, 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

91. Plaintiff repeats and realleges the allegations of paragraphs 1-90 as though fully set forth herein.

92. Par'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).

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

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

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

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

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

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

99. This case is an exceptional one, 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

100. Plaintiff repeats and realleges the allegations of paragraphs 1-99 as though fully set forth herein.

101. Par'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).

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

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

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

105. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will contributorily infringe the '106 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Par's Proposed Product in the United States. On information and belief, Par has had and continues to have knowledge that Par's Proposed Product is especially adapted for a use that infringes the '106 patent and that there is no substantial non-infringing use for Par's Proposed Product.

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

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

108. This case is an exceptional one, 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

109. Plaintiff repeats and realleges the allegations of paragraphs 1-108 as though fully set forth herein.

110. Par'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).

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

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

113. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will induce infringement of the '107 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Par's Proposed Product in the United States. On information and belief, upon FDA approval of Par's ANDA, Par will intentionally encourage acts of direct infringement with knowledge of the '107 patent and knowledge that its acts are encouraging infringement.

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

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

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

117. This case is an exceptional one, 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

118. Plaintiff repeats and realleges the allegations of paragraphs 1-117 as though fully set forth herein.

119. Par'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).

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

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

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

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

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

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

126. This case is an exceptional one, 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

127. Plaintiff repeats and realleges the allegations of paragraphs 1-126 as though fully set forth herein.

128. Par'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).

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

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

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

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

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

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

135. This case is an exceptional one, 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

136. Plaintiff repeats and realleges the allegations of paragraphs 1-135 as though fully set forth herein.

137. Par, 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 '182 patent. Par's actions with respect to its ANDA show that there is a substantial controversy, between the parties, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

138. Par'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).

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

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

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

142. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will contributorily infringe the '182 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Par's Proposed Product in the United States. On information and belief, Par has had and continues to have knowledge that Par's Proposed Product is especially adapted for a use that infringes the '182 patent and that there is no substantial non-infringing use for Par's Proposed Product.

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Jazz Pharmaceuticals respectfully requests the following relief:

(A) A Judgment be entered that Par has infringed the patents-in-suit by submitting ANDA No. 205403;

(B) A Judgment be entered that Par has infringed, and that Par's making, using, selling, offering to sell, or importing Par'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. 205403 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 Plaintiff is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Par 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 Par's Proposed Product until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Par, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any 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 Plaintiff is or becomes entitled;

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

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

(H) If Par engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Par's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Plaintiff Jazz Pharmaceuticals 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: December 27, 2013

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
SAUL EWING
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Jazz Pharmaceuticals, Inc.

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Gabriel P. Brier
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

Richard G. Greco
RICHARD G. GRECO PC
90 State Street, Suite 700
Albany, New York 12207
(212) 203-7625

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that the matters captioned *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 10-6108 (ES)(JAD) and *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 13-391 (ES)(JAD) are related to the matter in controversy because the matter in controversy involves the same plaintiff and the same patents.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: December 27, 2013

By: s/ Charles M. Lizza
Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Jazz Pharmaceuticals, Inc.

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Gabriel P. Brier
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

Richard G. Greco
RICHARD G. GRECO PC
90 State Street, Suite 700
Albany, New York 12207
(212) 203-7625