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Jazz Pharmaceuticals, Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

v.

**RANBAXY LABORATORIES LIMITED
and RANBAXY INC.,**

Defendants.

Civil Action No. _____

**COMPLAINT FOR
PATENT INFRINGEMENT**

(Filed Electronically)

Plaintiff Jazz Pharmaceuticals, Inc. (“Jazz Pharmaceuticals”), by its undersigned attorneys, for its Complaint against defendants Ranbaxy Laboratories Limited and Ranbaxy Inc. (collectively, “Ranbaxy”), 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 Ranbaxy’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”), and 8,731,963 (the “963 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 Ranbaxy Laboratories Limited is a company organized and existing under the laws of India, having a principal place of business at 12th Floor, Devika Towers, 6 Nehru Place, New Delhi, India.

4. On information and belief, Defendant Ranbaxy Laboratories Limited regularly transacts business within this judicial district. On information and belief, Ranbaxy Laboratories Limited develops numerous generic drugs for sale and use throughout the United States, including in this judicial district. On information and belief, Ranbaxy Laboratories Limited also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

5. On information and belief, Defendant Ranbaxy Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 600 College Road East, Princeton, New Jersey 08540.

6. On information and belief, Defendant Ranbaxy Inc. regularly conducts business in this judicial district, including marketing and selling pharmaceutical products. Further, on information and belief, Ranbaxy Inc. is an authorized agent for Ranbaxy Laboratories Limited, and a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

7. On information and belief, Defendants Ranbaxy Laboratories Limited and Ranbaxy Inc. acted collaboratively in the preparation and submission of ANDA No. 203351 to the FDA. On information and belief, Ranbaxy Laboratories Limited's submission of ANDA No. 203351 to the FDA was done at the direction, under the control, and for the direct benefit of Ranbaxy Inc.

8. On information and belief, following any FDA approval of ANDA No. 203351, Defendants Ranbaxy Laboratories Limited and Ranbaxy Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 203351 throughout the United States, and/or import such generic products into the United States.

Jurisdiction and Venue

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

10. This Court has personal jurisdiction over Ranbaxy Laboratories Limited by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Ranbaxy Laboratories Limited has purposefully availed 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. Further, on information and belief, Ranbaxy Laboratories Limited has customers in the State of New Jersey.

11. This Court has personal jurisdiction over Ranbaxy Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Ranbaxy Inc. has its principal place of business in Princeton, 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, Ranbaxy Inc. has customers in the State of New Jersey. Further, on information and belief, Ranbaxy Inc. is registered to conduct business in the State of New Jersey.

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

The Patent-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” 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.

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” 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.

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” 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.

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” 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.

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” 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.

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” 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.

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” 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

26. On May 20, 2014, the USPTO duly and lawfully issued the '963 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 '963 patent is attached hereto as Exhibit N.

The XYREM[®] Drug Product

27. 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.

28. 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, and '963 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

29. Pursuant to Section 505 of the FFDCA, Ranbaxy filed ANDA No. 203351 (“Ranbaxy’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 (“Ranbaxy’s Proposed Product”), before the patents-in-suit expire.

30. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Ranbaxy 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) (“Ranbaxy’s Paragraph IV Certification”), alleging that the claims of the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, and '963 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Ranbaxy’s ANDA.

31. No earlier than June 3, 2014, Jazz Pharmaceuticals received written notice of Ranbaxy's Paragraph IV Certification ("Ranbaxy's First Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B) concerning the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, and '182 patents. Ranbaxy's First Notice Letter alleged that the claims of the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, and '182 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Ranbaxy's ANDA. Ranbaxy's First Notice Letter also informed Jazz Pharmaceuticals that Ranbaxy seeks approval to market Ranbaxy's Proposed Product before the patents-in-suit expire.

32. No earlier than June 6, 2014, Jazz Pharmaceuticals received written notice of Ranbaxy's Paragraph IV Certification ("Ranbaxy's Second Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B) concerning '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, and '963 patents. Ranbaxy's Second Notice Letter alleged that the claims of the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, and '963 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Ranbaxy's ANDA. Ranbaxy's Second Notice Letter also informed Jazz Pharmaceuticals that Ranbaxy seeks approval to market Ranbaxy's Proposed Product before the patents-in-suit expire.

Count I: Infringement of the '431 Patent

33. Plaintiff repeats and realleges the allegations of paragraphs 1-32 as though fully set forth herein.

34. Ranbaxy, 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. Ranbaxy'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.

35. Ranbaxy'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).

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

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

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

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

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

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

42. 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

43. Plaintiff repeats and realleges the allegations of paragraphs 1-42 as though fully set forth herein.

44. Ranbaxy'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).

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

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

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

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

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

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

51. 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

52. Plaintiff repeats and realleges the allegations of paragraphs 1-51 as though fully set forth herein.

53. Ranbaxy'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).

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

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

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

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

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

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

60. 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

61. Plaintiff repeats and realleges the allegations of paragraphs 1-60 as though fully set forth herein.

62. Ranbaxy'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).

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

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

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

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

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

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

69. 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

70. Plaintiff repeats and realleges the allegations of paragraphs 1-69 as though fully set forth herein.

71. Ranbaxy'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).

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

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

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

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

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

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

78. 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

79. Plaintiff repeats and realleges the allegations of paragraphs 1-78 as though fully set forth herein.

80. Ranbaxy'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).

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

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

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

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

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

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

87. 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

88. Plaintiff repeats and realleges the allegations of paragraphs 1-87 as though fully set forth herein.

89. Ranbaxy, 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. Ranbaxy'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.

90. Ranbaxy'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).

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

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

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

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

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

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

97. 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

98. Plaintiff repeats and realleges the allegations of paragraphs 1-97 as though fully set forth herein.

99. Ranbaxy'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).

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

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

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

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

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

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

106. 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

107. Plaintiff repeats and realleges the allegations of paragraphs 1-106 as though fully set forth herein.

108. Ranbaxy'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).

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

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

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

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

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

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

115. 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

116. Plaintiff repeats and realleges the allegations of paragraphs 1-115 as though fully set forth herein.

117. Ranbaxy'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).

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

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

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

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

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

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

124. 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

125. Plaintiff repeats and realleges the allegations of paragraphs 1-124 as though fully set forth herein.

126. Ranbaxy'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).

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

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

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

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

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

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

133. 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

134. Plaintiff repeats and realleges the allegations of paragraphs 1-133 as though fully set forth herein.

135. Ranbaxy'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).

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

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

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

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

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

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

142. 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

143. Plaintiff repeats and realleges the allegations of paragraphs 1-142 as though fully set forth herein.

144. Ranbaxy'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).

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

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

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

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

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

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

151. 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 XIV: Infringement of the '963 Patent

152. Plaintiff repeats and realleges the allegations of paragraphs 1-151 as though fully set forth herein.

153. Ranbaxy'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).

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

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

156. Unless enjoined by this Court, upon FDA approval of Ranbaxy's ANDA, Ranbaxy will induce infringement of the '963 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ranbaxy's Proposed Product in the United States. On information and belief, upon FDA approval of Ranbaxy's ANDA, Ranbaxy will intentionally encourage acts of direct infringement with knowledge of the '963 patent and knowledge that its acts are encouraging infringement.

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

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

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

160. 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 Ranbaxy has infringed the patents-in-suit by submitting ANDA No. 203351;

(B) A Judgment be entered that Ranbaxy has infringed, and that Ranbaxy's making, using, selling, offering to sell, or importing Ranbaxy'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. 203351 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 Ranbaxy 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 Ranbaxy'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 Ranbaxy, 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 Ranbaxy's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Ranbaxy 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 Ranbaxy engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Ranbaxy'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: July 15, 2014

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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)(MAH), *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC, et al.*, Civil Action No. 13-391 (ES)(JAD), and *Jazz Pharmaceutucials, Inc. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 14-3235 (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: July 15, 2014

By: s/ Charles M. Lizza

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