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Jazz Pharmaceuticals, Inc.*

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

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

v.

**AMNEAL PHARMACEUTICALS, LLC,
PAR PHARMACEUTICAL, INC., SUN
PHARMACEUTICAL INDUSTRIES LTD.,
OHM LABORATORIES INC., 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 Sun Pharmaceutical Industries Ltd., Ohm Laboratories Inc., and Ranbaxy Inc., (collectively, “Sun”), Par Pharmaceutical, Inc., and Amneal Pharmaceuticals, LLC (collectively, “Defendants”), 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 Defendants’ filing of Abbreviated New Drug Applications (“ANDAs”) 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 No. 8,952,062 (the “’062 patent” or “the patent-in-suit”) owned by Jazz Pharmaceuticals.

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 Amneal Pharmaceuticals, LLC is a corporation organized under the laws of the State of Delaware, having a principal place of business at 440 U.S. Highway 22 East, Suite 104, Bridgewater, New Jersey 08807.

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

5. 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.

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

7. On information and belief, defendant Sun Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Acme Plaza, Andheri-Kurla Road, Andheri (E), Mumbai, 400 059, India.

8. On information and belief, Sun Pharmaceutical Industries Ltd. regularly transacts business within this Judicial District. On information and belief, Sun Pharmaceutical Industries Ltd. develops numerous generic drugs for sale and use throughout the United States, including in this Judicial District. On information and belief, Sun Pharmaceutical Industries Ltd. also prepares and/or aids in the preparation and submission of ANDAs to the FDA. Sun Pharmaceuticals Industries Ltd. and its predecessor Ranbaxy Laboratories Ltd. have litigated patent cases in this District in the past without contesting personal jurisdiction, and, in at least some of those actions, Sun Pharmaceuticals Industries Ltd. and its predecessor Ranbaxy Laboratories Ltd. have asserted counterclaims.

9. On information and belief, defendant Ohm Laboratories Inc. is a company organized and existing under the laws of the state of New Jersey, having a principal place of business at 14 Terminal Road, New Brunswick, NY 08901.

10. On information and belief, Ohm Laboratories Inc. regularly conducts business in this Judicial District, including marketing and selling pharmaceutical products. Further, on information and belief, Ohm Laboratories Inc. is an authorized agent for Sun Pharmaceutical Industries Ltd., and a wholly-owned subsidiary of Sun Pharmaceutical Industries Ltd.

11. 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.

12. On information and belief, 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 Sun Pharmaceutical Industries Ltd., and a wholly-owned subsidiary of Sun Pharmaceutical Industries Ltd. Ranbaxy Inc. has litigated patent cases in this District in the past without contesting personal jurisdiction, and, in at least some of those actions, Ranbaxy Inc. has asserted counterclaims.

13. On information and belief, defendants Sun Pharmaceutical Industries Ltd., Ohm Laboratories Inc., and Ranbaxy Inc. acted collaboratively in the preparation and submission of ANDA No. 203351 to the FDA. On information and belief, Ohm Laboratories Inc.'s and Ranbaxy Inc.'s submission of ANDA No. 203351 to the FDA was done at the direction, under the control, and for the direct benefit of Sun Pharmaceutical Industries Ltd.

Jurisdiction and Venue

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

15. This Court has personal jurisdiction over Amneal Pharmaceuticals, LLC by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Amneal Pharmaceuticals, LLC has purposefully availed itself of this forum by, among other things, operating its headquarters in the State of New Jersey, 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. Amneal Pharmaceuticals, LLC currently is litigating, and has litigated in the past, patent cases in this District without contesting personal jurisdiction. In at least some of those actions, Amneal Pharmaceuticals, LLC has asserted counterclaims. Further, on information and belief, Amneal Pharmaceuticals, LLC has customers in the State of New Jersey.

16. This Court has personal jurisdiction over Par Pharmaceutical, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Par Pharmaceutical, Inc. 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. Par Pharmaceutical, Inc. currently is litigating, and has litigated in the past, patent cases in this District without contesting personal jurisdiction. In at least some of those actions, Par Pharmaceutical, Inc. has asserted counterclaims. Also, on information and belief, Par Pharmaceutical, Inc. has customers in the State of New Jersey. Further, on information and belief, Par Pharmaceutical, Inc. is registered to conduct business in the State of New Jersey.

17. This Court has personal jurisdiction over Sun Pharmaceutical Industries Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Pharmaceutical Industries Ltd. 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. Sun Pharmaceutical Industries Ltd. currently is litigating, and has litigated in the past, patent cases in this District without contesting personal jurisdiction. In at least some of those actions, Sun Pharmaceutical Industries Ltd. has asserted counterclaims. Further, on information and belief, Sun Pharmaceutical Industries Ltd. has customers in the State of New Jersey.

18. This Court has personal jurisdiction over Ohm Laboratories Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and

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

19. 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. Ranbaxy Inc. currently is litigating, and has litigated in the past, patent cases in this District without contesting personal jurisdiction. In at least some of those actions, Ranbaxy Inc. has asserted counterclaims. 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.

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

The Patent-In-Suit

21. 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 A.

The XYREM[®] Drug Product

22. 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 ’062 patent cover, *inter alia*, methods of use and administration of sodium oxybate or pharmaceutical compositions containing sodium oxybate. Jazz Pharmaceuticals owns the ’062 patent.

23. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patent-in-suit is 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

Amneal

24. Pursuant to Section 505 of the FFDCA, Amneal filed ANDA No. 203631 (“Amneal’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 (“Amneal’s Proposed Product”), before the patent-in-suit expires.

25. In connection with the filing of its ANDA as described in the preceding paragraph, Amneal has provided written certifications to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Amneal’s Paragraph IV Certifications”), alleging that the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Amneal’s ANDA.

26. No earlier than March 25, 2015, Jazz Pharmaceuticals received written notice of Amneal’s Paragraph IV Certification (“Amneal’s Notice Letter”) pursuant to 21 U.S.C. § 355(j)(2)(B) with respect to the patent-in-suit. Amneal’s Notice Letter alleged that

the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Amneal's ANDA. Amneal's Notice Letter also informed Jazz Pharmaceuticals that Amneal seeks approval to market Amneal's Proposed Product before the patent-in-suit expires.

Par

27. 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 patent-in-suit expires.

28. 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 patent-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Par's ANDA.

29. No earlier than March 23, 2015, 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 patent-in-suit 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 patent-in-suit expires.

Sun

30. Pursuant to Section 505 of the FFDCA, Sun filed ANDA No. 203351 ("Sun'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 ("Sun's Proposed Product") (together

with Amneal's Proposed Product and Par's Proposed Product, "Defendants' Proposed Products"), before the patent-in-suit expires.

31. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Sun has provided a written certification to the FDA, as called for by Section 505 of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Sun's Paragraph IV Certification"), alleging that the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Sun's ANDA.

32. No earlier than March 26, 2015, Jazz Pharmaceuticals received written notice of Sun's Paragraph IV Certification ("Sun's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B) concerning the patent-in-suit. Sun's Notice Letter alleged that the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Sun's ANDA. Sun's Notice Letter also informed Jazz Pharmaceuticals that Sun seeks approval to market Sun's Proposed Product before the patent-in-suit expires.

Count I: Amneal's Infringement of the '062 Patent

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

34. Amneal'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).

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

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

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

38. Unless enjoined by this Court, upon FDA approval of Amneal's ANDA, Amneal will contributorily infringe the '062 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Amneal's Proposed Product in the United States. On information and belief, Amneal has had and continues to have knowledge that Amneal's Proposed Product is especially adapted for a use that infringes the '062 patent and that there is no substantial non-infringing use for Amneal's Proposed Product.

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

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

41. 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: Par's Infringement of the '062 Patent

42. Plaintiff repeats and realleges the allegations of paragraphs 1-41 as though fully set forth herein.

43. 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 '062 patent, constitutes infringement of one or more of the 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 Par's infringement of the '062 patent.

45. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will infringe the '062 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.

46. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will induce infringement of the '062 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 '062 patent and knowledge that its acts are encouraging infringement.

47. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will contributorily infringe the '062 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 '062 patent and that there is no substantial non-infringing use for Par's Proposed Product.

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

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

50. 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: Sun's Infringement of the '062 Patent

51. Plaintiff repeats and realleges the allegations of paragraphs 1-50 as though fully set forth herein.

52. Sun'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).

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

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

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

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

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

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

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

59. 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 Defendants have infringed the patent-in-suit by submitting their respective ANDAs;

(B) A Judgment be entered that Defendants have infringed, and that Defendants' making, using, selling, offering to sell, or importing their Proposed Products will infringe one or more claims of the patent-in-suit;

(C) An Order that the effective date of FDA approval of ANDA Nos. 203631, 205403, and 203351 be a date which is not earlier than the later of the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Defendants' Proposed Products until after the expiration of the patent-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 Defendants, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods as claimed in the patent-in-suit, or from actively inducing or contributing to the infringement of any claim of the patent-in-suit, until after the expiration of the patent-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 Defendants' Proposed Products will directly infringe, induce and/or contribute to infringement of the patent-in-suit;

(G) To the extent that Defendants have committed any acts with respect to the methods claimed in the patent-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 Defendants engage in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Defendants' Proposed Products prior to the expiration of the patent-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: May 7, 2015

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