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

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

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS, LLC,

Defendant.

Civil Action No. _____

**COMPLAINT FOR
PATENT INFRINGEMENT**

(Filed Electronically)

Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, “Jazz Pharmaceuticals”), by their undersigned attorneys, for their Complaint against defendant Amneal Pharmaceuticals, LLC (“Amneal”), allege 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 Amneal’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. 9,050,302 (the “302 patent”), owned by Jazz Pharmaceuticals (“the patent-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. Plaintiff Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, having a principal place of business at One Burlington Road, Fourth Floor, Connaught House, Dublin, Ireland 4.

4. On information and belief, defendant Amneal 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.

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 Amneal by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Amneal 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 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 has asserted counterclaims. Further, on information and belief, Amneal has customers 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 June 9, 2015, the USPTO duly and lawfully issued the '302 patent, entitled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters." A copy of the '302 patent is attached hereto as Exhibit A.

The XYREM[®] Drug Product

9. 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 '302 patent cover, *inter alia*, methods of use and administration of sodium oxybate or pharmaceutical compositions containing sodium oxybate. Jazz Pharmaceuticals owns the '302 patent.

10. 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[®].

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

Acts Giving Rise to This Suit

12. Pursuant to Section 505 of the FFDCA, Amneal filed ANDA No. 203631 ("Amneal's ANDA") seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of 500 mg/mL sodium oxybate oral solution ("Amneal's Proposed Product"), before the patent-in-suit expires.

13. 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 FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Amneal’s Paragraph IV Certifications”), alleging that the claims of the patent-in-suit and other Orange-Book-listed patents owned by Jazz Pharmaceuticals are invalid, unenforceable, and/or will not be infringed by the activities described in Amneal’s ANDA.

14. No earlier than July 23, 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.

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

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

Count for Infringement of the ’302 Patent

17. Jazz Pharmaceuticals repeats and realleges the allegations of paragraphs 1-16 as though fully set forth herein.

18. Amneal’s submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution,

prior to the expiration of the '302 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

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

20. Unless enjoined by this Court, upon FDA approval of Amneal's ANDA, Amneal will infringe the '302 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.

21. Unless enjoined by this Court, upon FDA approval of Amneal's ANDA, Amneal will induce infringement of the '302 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 '302 patent and knowledge that its acts are encouraging infringement.

22. Unless enjoined by this Court, upon FDA approval of Amneal's ANDA, Amneal will contributorily infringe the '302 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 '302 patent and that there is no substantial non-infringing use for Amneal's Proposed Product.

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

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

25. 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, Jazz Pharmaceuticals respectfully requests the following relief:

(A) A Judgment be entered that Amneal has infringed the patent-in-suit by submitting ANDA No. 203631;

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

(C) An Order that the effective date of FDA approval of ANDA No. 203631 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 Jazz Pharmaceuticals is or becomes entitled;

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

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Amneal, its 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 Jazz Pharmaceuticals is or becomes entitled;

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

(G) To the extent that Amneal has 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 Jazz Pharmaceuticals be awarded damages for such acts;

(H) If Amneal engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Amneal's Proposed Product prior to the expiration of the patent-in-suit, a Judgment awarding damages to 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: September 2, 2015

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