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Jazz Pharmaceuticals, Inc. and
Jazz Pharmaceuticals Ireland Limited

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. 8,731,963 (the "'963 patent"),

8,772,306 (the "'306 patent"), and 8,859,619 (the "'619 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. 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 May 20, 2014, the USPTO duly and lawfully issued the '963 patent, entitled "Sensitive Drug Distribution System and Method." A copy of the '963 patent is attached hereto as Exhibit A.

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

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

The XYREM® Drug Product

11. 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*, methods of use and administration of sodium oxybate or pharmaceutical compositions containing sodium oxybate. Jazz Pharmaceuticals owns the patents-in-suit.

12. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to XYREM®.

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

Acts Giving Rise to This Suit

14. 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 patents-in-suit expire.

15. 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 patents-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.

16. No earlier than January 16, 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 patents-in-suit. Amneal's Notice Letter alleged that the claims of the patents-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 patents-in-suit expire.

Count I: Infringement of the '963 Patent

17. Plaintiffs repeat and reallege 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 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).

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

20. Unless enjoined by this Court, upon FDA approval of Amneal's ANDA, Amneal will infringe the '963 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 '963 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 '963 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 '963 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 '963 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 '963 patent is not enjoined.

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

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