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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 No. 8,731,963 (the "'963 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 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 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 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 patent-in-suit cover, *inter alia*, computer-implemented systems for the administration of sodium oxybate or pharmaceutical compositions containing sodium oxybate. Jazz Pharmaceuticals owns the patent-in-suit.

10. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '963 patent 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

11. 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.

12. 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.

13. No earlier than July 3, 2014, 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.

Count for Infringement of the '963 Patent

14. Plaintiff repeats and realleges the allegations of paragraphs 1-13 as though fully set forth herein.

15. 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 '963 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

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

17. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will infringe the '963 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.

18. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will induce infringement of the '963 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 '963 patent and knowledge that its acts are encouraging infringement.

19. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will contributorily infringe the '963 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 '963 patent and that there is no substantial non-infringing use for Par's Proposed Product.

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

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

22. 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 patent-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 patent-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 patent-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

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