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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC., **Plaintiff,** **v.** **ROXANE LABORATORIES, 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 Roxane Laboratories, Inc. ("Roxane"), 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 Roxane'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. 8,263,650 (the "'650 patent") 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. Defendant Roxane is a corporation organized under the laws of Nevada, having a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228.

4. On information and belief, Roxane is registered to do business in the State of New Jersey, and maintains a registered agent for service of process in New Jersey. On information and belief, Roxane regularly transacts business within this judicial district. Further, on information and belief, Roxane develops numerous generic drugs for sale and use throughout the United States, including in this judicial district. Roxane has litigated patent cases in this district in the past without contesting personal jurisdiction, and, in at least some of those actions, Roxane 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 Roxane by virtue of, *inter alia,* its systematic and continuous contacts with the State of New Jersey. On information and belief, Roxane 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, Roxane 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 September 11, 2012, the United States Patent and Trademark Office ("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 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 '650 patent cover, *inter alia*, methods of use and administration of sodium oxybate or pharmaceutical compositions containing sodium oxybate. Jazz Pharmaceuticals owns the '650 patent.

10. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '650 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, Roxane filed ANDA No. 202-090 ("Roxane'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 ("Roxane's Proposed Product"), before the '650 patent expires.

12. In connection with the filing of its ANDA as described in the preceding paragraph, Roxane 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), alleging that the claims of the '650 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Roxane's ANDA.

13. No earlier than October 5, 2012, Roxane sent written notice of its ANDA certification to Jazz Pharmaceuticals ("Roxane's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Roxane's Notice Letter alleged that the claims of the '650 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Roxane's ANDA. Roxane's Notice Letter also informed Jazz Pharmaceuticals that Roxane seeks approval to market Roxane's Proposed Product before the '650 patent expires.

Count for Infringement of the '650 Patent

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

15. Roxane'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).

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

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

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

information and belief, upon FDA approval of Roxane's ANDA, Roxane will intentionally encourage acts of direct infringement with knowledge of the '650 patent and knowledge that its acts are encouraging infringement.

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

20. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Roxane's infringement of the '650 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 Roxane has infringed the '650 patent by submitting ANDA No. 202-090;

(B) A Judgment be entered that Roxane has infringed, and that Roxane's making, using, selling, offering to sell, or importing Roxane's Proposed Product will infringe one or more claims of the '650 patent;

(C) An Order that the effective date of FDA approval of ANDA No. 202-090 be a date which is not earlier than the later of the expiration of the '650 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Roxane 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 Roxane's Proposed Product until after the expiration of the '650 patent, 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 Roxane, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods as claimed in the '650 patent, or from actively inducing or contributing to the infringement of any claim of the '650 patent, until after the expiration of the '650 patent, 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 Roxane's Proposed Product will directly infringe, induce and/or contribute to infringement of the '650 patent;

(G) To the extent that Roxane has committed any acts with respect to the methods claimed in the '650 patent, 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 Roxane engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Roxane's Proposed Product prior to the expiration of the '650 patent, 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: October 26, 2012

By: s/ Charles M. Lizza

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