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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC., **Plaintiff,** **v.** **WATSON 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 Watson Laboratories, Inc. ("Watson"), 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 Watson'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. 8,859,619 ("the '619 patent") and 8,952,062 ("the '062 patent") owned by Jazz Pharmaceuticals (collectively, "the patents-in-suit").

The Parties

2. Plaintiff Jazz Pharmaceuticals, Inc. 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 Watson is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

4. On information and belief, Watson develops numerous generic drugs for sale and use throughout the United States, including in this Judicial District. Watson has litigated patent cases in this District in the past without contesting personal jurisdiction, and, in at least some of those actions, Watson 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 Watson by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Watson has its principal place of business in Parsippany, 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, Watson has customers in the State of New Jersey. Further, on information and belief, Watson 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 Patents-In-Suit

8. On October 14, 2014, the United States Patent and Trademark Office ("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 A.

9. 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 B.

The XYREM® Drug Product

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

11. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '619 and '062 patents are 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

12. Pursuant to Section 505 of the FFDCA, Watson filed ANDA No. 204952 ("Watson'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 ("Watson's Proposed Product"), before the patents-in-suit expire.

13. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Watson 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) ("Watson's Paragraph IV Certification"), alleging that the claims of the '619 and '062 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Watson's ANDA.

14. No earlier than May 14, 2105, Jazz Pharmaceuticals received written notice of Watson's Paragraph IV Certification ("Watson's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Watson's Notice Letter alleged that the claims of the '619 and '062 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Watson's ANDA. Watson's Notice Letter also informed Jazz Pharmaceuticals that Watson's seeks approval to market Watson's Proposed Product before the patents-in-suit expire.

Count I: Infringement of the '619 Patent

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

16. Watson, through its submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks 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 '619 patent. Watson's actions with respect to its ANDA show that there is a substantial controversy between the parties of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

17. Watson'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 '619 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

18. There is a justiciable controversy between the parties hereto as to the infringement of the ’619 patent.

19. Unless enjoined by this Court, upon FDA approval of Watson’s ANDA, Watson will infringe the ’619 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Watson’s Proposed Product in the United States.

20. Unless enjoined by this Court, upon FDA approval of Watson’s ANDA, Watson will induce infringement of the ’619 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Watson’s Proposed Product in the United States. On information and belief, upon FDA approval of Watson’s ANDA, Watson will intentionally encourage acts of direct infringement with knowledge of the ’619 patent and knowledge that its acts are encouraging infringement.

21. Unless enjoined by this Court, upon FDA approval of Watson’s ANDA, Watson will contributorily infringe the ’619 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Watson’s Proposed Product in the United States. On information and belief, Watson has had and continues to have knowledge that Watson’s Proposed Product is especially adapted for a use that infringes the ’619 patent and that there is no substantial non-infringing use for Watson’s Proposed Product.

22. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Watson’s infringement of the ’619 patent is not enjoined.

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

24. 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: Infringement of the ’062 Patent

25. Plaintiff repeats and realleges the allegations of paragraphs 1-24 as though fully set forth herein.

26. Watson’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).

27. There is a justiciable controversy between the parties hereto as to the infringement of the ’062 patent.

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

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

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

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

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

33. 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 respectfully requests the following relief:

(A) A Judgment be entered that Watson has infringed the patents-in-suit by submitting ANDA No. 204952;

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

(C) An Order that the effective date of FDA approval of ANDA No. 204952 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Watson 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 Watson's Proposed Product until after the expiration of the patents-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 Watson, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit,

until after the expiration of the patents-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 Watson's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Watson has committed any acts with respect to the compositions and methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiff be awarded damages for such acts;

(H) If Watson engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Watson's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Plaintiff 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: June 26, 2015

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that the matters captioned *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 10-6108 (ES)(MAH), *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC et al.*, Civil Action No. 13-391 (ES)(JAD), *Jazz Pharmaceuticals, Inc. et al. v. Roxane Laboratories, Inc.*, Civil Action No. 15-1360 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 15-3217 (ES)(JAD), and *Jazz Pharmaceuticals, Inc. et al. v. Roxane Laboratories, Inc.*, Civil Action No. 15-3684 (ES)(JAD) are related to the matter in controversy because the matter in controversy involves defendants who filed Abbreviated New Drug Applications seeking to market generic versions of the same drug product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: June 26, 2015

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