IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 1:21-cv-01594-GBW

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Jazz Pharmaceuticals" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Avadel CNS Pharmaceuticals, LLC ("Avadel" or "Defendant"), 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 Avadel's filing of a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a sodium oxybate drug product prior to the expiration of United States Patent No. 11,147,782 (the "'782 patent" or "the patent-in-suit"), and the FDA's subsequent approval thereof.

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 3170 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 Waterloo Exchange, Waterloo Road, Dublin, Ireland 4.

4. On information and belief, Defendant Avadel CNS Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. On information and belief, Defendant is in the business of, *inter alia*, developing, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its affiliates, including Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, and Avadel Management Corporation.

5. On information and belief, Defendant Avadel CNS Pharmaceuticals, LLC has made, used, offered to sell, and/or sold the product that is the subject of its NDA for a sodium oxybate product throughout the United States, and/or imported such a product into the United States and will make, use, offer to sell, and/or sell the product that is the subject of its NDA for a sodium oxybate product throughout the United States, and/or import such a product into the United States.

Jurisdiction and Venue

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. On information and belief, Defendant is subject to personal jurisdiction in Delaware because Defendant has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Defendant is a limited liability company organized and existing under the laws of the State of Delaware. On information

and belief, Defendant manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Defendant is registered to do business in Delaware (business identification number 7734658) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

8. On information and belief, by virtue of, *inter alia*, Defendant's continuous and systematic contacts with Delaware, including, but not limited to, the above-described contacts, and the actions on behalf of Defendant in connection with its NDA seeking FDA approval to commercially market a sodium oxybate drug product, this Court has personal jurisdiction over Defendant. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with Delaware law.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patent-In-Suit

10. On October 19, 2021, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '782 patent entitled, "GHB formulation and method for its manufacture." A copy of the '782 patent is attached hereto as Exhibit A.

Background

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 '782 patent cover, *inter alia*, pharmaceutical compositions containing sodium oxybate. Jazz Pharmaceuticals owns the patent-in-suit.

Acts Giving Rise to This Suit

12. Pursuant to Section 505(b)(2) of the FFDCA, Avadel filed an NDA ("Avadel's NDA") seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of a sodium oxybate product ("Avadel's Proposed Product"), before the patent-in-suit expires.

13. On December 16, 2020, Avadel announced the submission of its NDA to the FDA. On information and belief, on February 26, 2021, the FDA notified Avadel of formal acceptance of Avadel's NDA with an assigned Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021.[1] On October 15, 2021, Avadel announced that the FDA notified the company that the review of Avadel's NDA was still ongoing and that a new target action date would be provided as soon as possible.[2]

14. Avadel has identified its Proposed Product using both the code name FT218[3] and the commercial name LUMRYZ™.

15. Avadel has published data comparing the pharmacokinetic properties of Avadel's Proposed Product with twice-nightly sodium oxybate (*i.e.*, XYREM®).[4]

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[1] *See* Avadel's 2020 Annual Report at p. 7 (available at https://www.sec.gov/ix?doc=/Archives/edgar/data/1012477/000101247721000004/avdl-20201231.htm)

[2] *See* https://investors.avadel.com/news-releases/news-release-details/avadel-pharmaceuticals-announces-ongoing-fda-review-nda-ft218

[3] *See id.*

[4] Seiden, et al., *Pharmacokinetics of FT218, a Once-Nightly Sodium Oxybate Formulation in Healthy Adults*, Clin. Ther. 2021 Feb 22; S0149-2918(21)00044-8; doi: 10.1016/j.clinthera.2021.01.017, attached hereto as Exhibit B.

16. Avadel owns U.S. Patent No. 10,736,866 ("Avadel's '866 patent") entitled "Modified Release Gamma-Hydroxybutyrate Formulations Having Improved Pharmacokinetics," attached hereto as Exhibit C.

17. On information and belief, Avadel's published data concerning the pharmacokinetic properties of Avadel's Proposed Product correspond to the Examples of Avadel's '866 patent.

18. On information and belief, Avadel's Proposed Product is an embodiment of the claims of Avadel's '866 patent.

19. On information and belief, the formulations of gamma-hydroxybutyrate described in Avadel's '866 patent include immediate release particles comprising GHB, modified release particles comprising GHB, a viscosity enhancing agent, and an acid.[5]

20. On information and belief, Avadel's Proposed Product, includes immediate release particles comprising GHB, modified release particles comprising GHB, a viscosity enhancing agent, and an acid.[6]

21. On information and belief, Avadel's Proposed Product, FT218 or LUMRYZ™, is covered by Jazz Pharmaceuticals' '782 patent.

22. On information and belief, Avadel has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Avadel's Proposed Product prior to expiration of the patent-in-suit. For example, on information and belief, Avadel

[5] *See* Avadel's '866 patent at 24:1-5 ("In a second principal structural embodiment the invention provides a modified release formulation of gamma-hydroxybutyrate comprising immediate release and modified release portions, a suspending or viscosifying agent, and an acidifying agent."); *see also id.* at 32:64-33:3; *id.* at 34:18-25.

[6] *See id.*

received permission from FDA to import into the United States commercially manufactured batches of its Proposed Product.

23. On information and belief, on May 1, 2023, Avadel received final approval of its NDA from the FDA, and Avadel has indicated to Jazz Pharmaceuticals that it intends to commercialize its Proposed Product on or about June 1, 2023.

Count for Infringement of the '782 Patent

24. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

25. Avadel, by the submission of its NDA to the FDA, sought approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel's Proposed Product, prior to the expiration of the '782 patent.

26. Avadel's NDA had been pending before the FDA since at least December 16, 2020, the date that Avadel announced the submission of its NDA to the FDA.

27. On May 1, 2023, Avadel received final approval from the FDA, and Avadel has indicated to Jazz Pharmaceuticals that it intends to commercialize its Proposed Product on or about June 1, 2023.

28. There is a justiciable controversy between the parties hereto as to the infringement of the '782 patent.

29. Avadel has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Avadel's Proposed Product prior to the expiration of the '782 patent. For example, on information and belief, Avadel received permission from FDA to import into the United States commercially manufactured batches of its Proposed Product and has imported the product.

30. Avadel has infringed and will infringe one or more claims of the '782 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States.

31. Avadel has induced infringement and will induce infringement of one or more claims of the '782 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, Avadel has encouraged and will encourage acts of direct infringement with knowledge of the '782 patent and knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the '782 patent.

32. Avadel has contributorily infringed and will contributorily infringe one or more claims of the '782 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, Avadel has had and continues to have knowledge that Avadel's Proposed Product is especially adapted for a use that infringes one or more claims of the '782 patent and that there is no substantial non-infringing use for Avadel's Proposed Product.

33. Plaintiffs will be substantially and irreparably damaged and harmed if Avadel's infringement of the '782 patent is not enjoined.

34. Plaintiffs are entitled to a judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Avadel's Proposed Product prior to expiration of the '782 patent by Avadel has constituted and will constitute direct infringement, induced infringement, and/or contributory infringement of the '782 patent.

35. Plaintiffs do not have an adequate remedy at law.

36. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

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

(B) A permanent injunction enjoining Avadel and its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from making, using, selling, offering to sell, and/or importing Avadel's Proposed Product until after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

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

(D) To the extent that Avadel has committed any acts with respect to the formulations claimed in the patent-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiffs be awarded damages for such acts;

(E) A Judgment awarding damages to Plaintiffs resulting from Avadel's infringement of the patent-in-suit pursuant to 35 U.S.C. §284, including no less than a reasonable royalty, together with pre-judgment and post-judgment interest and costs as fixed by the Court;

(F) That the Court award, in lieu of a permanent injunction, an ongoing royalty;

(G) That the Court order an accounting of damages;

(H) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(I) Costs and expenses in this action; and

(J) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

Attorneys for Plaintiffs
Jazz Pharmaceuticals, Inc. and
Jazz Pharmaceuticals Ireland Limited

OF COUNSEL:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Andrew S. Chalson
Gabriel P. Brier
Frank C. Calvosa
Nicholas A. LoCastro
Krista M. Rycroft
Quentin Jorgensen
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

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