IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL PHARMACEUTICALS PLC, AVADEL US HOLDINGS, INC., AVADEL SPECIALTY PHARMACEUTICALS, LLC, AVADEL LEGACY PHARMACEUTICALS, LLC, AVADEL MANAGEMENT CORPORATION AND AVADEL CNS PHARMACEUTICALS, LLC. Defendants.	C.A. No. 21-691-MN

ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT, DEFENSES AND COUNTERCLAIMS

Preliminary Statement

This is not the typical pharmaceutical patent infringement case involving a defendant who is seeking U.S. Food and Drug Administration ("FDA") approval to market a generic version of the plaintiff's brand name drug. The innovative drug product in this case is owned by the Defendant, Avadel CNS Pharmaceuticals, LLC ("Avadel"), whose Irish affiliate ("Avadel Ireland") developed a revolutionary new ***once***-nightly formulation of sodium oxybate (currently designated as FT218). Avadel has submitted a New Drug Application ("NDA") to FDA for purposes of seeking approval of its branded medication, FT218, for the treatment of excessive daytime sleepiness ("EDS") and cataplexy in adults with narcolepsy. Plaintiff Jazz Pharmaceuticals, Inc. ("Jazz") has for almost two decades marketed and sold immediate-release, ***twice***-nightly sodium oxybate formulations, first under the trade name Xyrem® and more recently under the trade name Xywav™. Both of Jazz's sodium oxybate products require narcolepsy

patients to take a first dose right before bedtime, and to then wake up in the middle of the night and take a second dose.

Because narcolepsy is a sleep disorder, waking up in the middle of the night for treatment is counterintuitive and represents a major problem for these patients. There is, therefore, a significant need that is unmet by Jazz's twice-nightly sodium oxybate products; namely, a once-nightly sodium oxybate drug product. Notably, Jazz told the marketplace of this unmet need and tried in vain to formulate a product with the requisite bioavailability for once-nightly dosing, but utterly failed to develop such a product. *See* Jazz Pharmaceuticals plc, Annual Report (Form 10-k) (Feb. 23, 2016), *available at* https://investor.jazzpharma.com/node/14886/html (Jazz is "also pursuing other activities related to the potential development of options for narcolepsy patients that would provide clinically meaningful improvements compared to Xyrem, including once-nightly dosing.").

Avadel Ireland ultimately succeeded where Jazz failed. Avadel Ireland developed FT218, its once-nightly sodium oxybate formulation. Recognizing its potential superiority over Jazz's existing twice-nightly formulations, the FDA has granted FT218 Orphan Drug Designation for the treatment of narcolepsy. With approval and a grant of Orphan Drug Exclusivity, FT218 would be awarded a seven-year period of market exclusivity in the United States.

Avadel Ireland conducted its own extensive clinical testing in support of Avadel's NDA for FT218. Avadel Ireland initially conducted a Phase 1 pharmacokinetic crossover study and an additional comparative, open-label, 2-period, randomized 2 sequence, crossover study on the safety and bioavailability of FT218. Avadel Ireland also conducted the REST-ON Trial, a pivotal, double-blind, randomized, placebo-controlled Phase 3 trial, to assess the efficacy and safety of FT218 in the treatment of EDS and cataplexy in narcolepsy patients. FT218 met all three co-

primary endpoints in that Phase 3 trial, demonstrating highly significant and clinically meaningful improvements compared to placebo, and was well tolerated with low rates of commonly known adverse reactions.

Avadel is currently conducting additional clinical testing beyond what is required for FDA approval, including its open-label extension RESTORE study, underscoring its commitment to patients and the narcolepsy therapeutic area. Avadel is committed to its mission of liberating patients with narcolepsy from middle of the night dosing.

Jazz's suit is not meant to prevent a generic copy of a branded drug, as in the typical Hatch-Waxman Act lawsuit. Far from it. Rather, Jazz's suit targets Avadel's introduction of its own branded, groundbreaking FT218 product for narcolepsy patients. Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals, LLC (collectively, "Defendants") deny that they infringe, have infringed, or will infringe any valid claim of the asserted patents, deny that there is any legitimate basis for the lawsuit brought by Jazz, deny that Jazz is entitled to any relief, and deny the allegations and characterizations in Jazz's Complaint unless expressly admitted as follows:

Nature of the Action

1. This is an action for patent infringement and for a declaratory judgement of patent infringement under the patent laws of the United States, 35 U.S.C. §100, et seq. and 28 U.S.C. §§ 2201 and 2202, 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 Nos. 8,731,963 (the "'963 patent"), 10,758,488 (the "'488 patent"), 10,813,885 (the "'885 patent"), 10,959,956 (the "'956 patent"), and 10,966,931 (the "'931 patent") owned by Jazz Pharmaceuticals (collectively, "the patents-in-suit").

ANSWER: Defendants admit that the Complaint purports to allege an action for patent infringement and for a declaratory judgment of patent infringement under the patent laws of the

United States, 35 U.S.C. §100, et seq. and 28 U.S.C. §§ 2201 and 2202, involving United States Patent Nos. 8,731,963 (the "'963 patent"), 10,758,488 (the "'488 patent"), 10,813,885 (the "'885 patent"), 10,959,956 (the "'956 patent"), and 10,966,931 (the "'931 patent") (collectively, "the patents-in-suit"), each of which states on its face that it is owned by Jazz Pharmaceuticals. Defendants admit that Avadel filed an NDA with the FDA seeking approval to commercially market FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the patents-in-suit have not yet expired. Defendants deny that the Complaint properly states a claim for patent infringement. Except as otherwise admitted, the allegations are denied as stated.

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.

ANSWER: Defendants lack sufficient information to form a belief as to the truth of the allegations in Paragraph 2, and therefore deny them.

3. On information and belief, Defendant Avadel Pharmaceuticals plc is a corporation organized and existing under the laws of Ireland, having a principal place of business at 10 Earlsfort Terrace, Dublin 2, Ireland, D02 T380. On information and belief, Avadel Pharmaceuticals plc is in the business of, *inter alia*, developing, manufacturing, marketing, 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, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC.

ANSWER: Defendants admit that Avadel Pharmaceuticals plc is a corporation organized and existing under the laws of Ireland and has its principal place of business at 10 Earlsfort Terrace, Dublin 2, Ireland, D02 T380. Except as otherwise admitted, the allegations are denied as stated.

4. On information and belief, Defendant Avadel US Holdings, Inc. is a corporation 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, Avadel US Holdings, Inc. 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 Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC.

ANSWER: Defendants admit that Avadel US Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. Except as otherwise admitted, the allegations are denied as stated.

5. On information and belief, Avadel US Holdings, Inc. is a wholly-owned subsidiary of Avadel Pharmaceuticals plc.

ANSWER: Admitted.

6. On information and belief, Defendant Avadel Specialty 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, Avadel Specialty Pharmaceuticals, LLC 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 Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC.

ANSWER: Defendants admit that Avadel Specialty Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Except as otherwise admitted, the allegations are denied as stated.

7. On information and belief, Defendant Avadel Legacy 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, Avadel Legacy Pharmaceuticals, LLC 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 Management Corporation, and Avadel CNS Pharmaceuticals LLC.

ANSWER: Defendants admit that Avadel Legacy Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware and has its principal place

of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. Except as otherwise admitted, the allegations are denied as stated.

8. On information and belief, Defendant Avadel Management Corporation is a corporation 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, Avadel Management Corporation 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 CNS Pharmaceuticals LLC.

ANSWER: Defendants admit that Avadel Management Corporation is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. Except as otherwise admitted, the allegations are denied as stated.

9. 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, Avadel CNS Pharmaceuticals LLC 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.

ANSWER: Defendants admit that Avadel CNS Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware and has its principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. Defendants admit that Avadel CNS Pharmaceuticals, LLC develops, manufactures, markets, imports, offers for sale, and sells pharmaceutical products throughout the United States. Defendants deny the remaining allegations in Paragraph 9.

10. On information and belief, Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC are wholly-owned subsidiaries of Avadel US Holdings, Inc.

ANSWER: Admitted.

11. On information and belief, following any FDA approval of their NDA for a sodium oxybate product, Defendants Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC will work in concert with one another to make, use, offer to sell, and/or sell the product that is the subject of their NDA for a sodium oxybate product throughout the United States, and/or import such a product into the United States.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants deny the remaining allegations in Paragraph 11.

Jurisdiction and Venue

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: The allegations in Paragraph 12 state legal conclusions to which no response is required. To the extent a response is required, Defendants do not dispute subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. On information and belief, Avadel Pharmaceuticals plc is subject to personal jurisdiction in Delaware because Avadel Pharmaceuticals plc 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. On information and belief, Avadel Pharmaceuticals plc manufactures, markets, 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 Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

ANSWER: The allegations in Paragraph 13 state legal conclusions to which no response is required. To the extent a response is required, Defendants do not dispute that Avadel Pharmaceuticals plc is subject to personal jurisdiction in Delaware for purposes of this action only.

14. On information and belief, Avadel US Holdings, Inc. is subject to personal jurisdiction in Delaware because Avadel US Holdings, Inc. 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. Avadel US Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Avadel US Holdings, Inc. 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 Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel US Holdings, Inc. is registered to do business in Delaware (business identification number 5123065) 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.

ANSWER: Defendants admit that Avadel US Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware. Defendants do not dispute that Avadel US Holdings, Inc. is subject to personal jurisdiction in Delaware for purposes of this action only. Except as otherwise admitted, the allegations are denied as stated.

15. On information and belief, Avadel Specialty Pharmaceuticals, LLC is subject to personal jurisdiction in Delaware because Avadel Specialty Pharmaceuticals, LLC 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. Avadel Specialty Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Avadel Specialty Pharmaceuticals, LLC 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 Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel Specialty Pharmaceuticals, LLC is registered to do business in Delaware (business identification number 6507288) 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.

ANSWER: Defendants admit that Avadel Specialty Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Defendants do not dispute that Avadel Specialty Pharmaceuticals, LLC is subject to personal jurisdiction in Delaware for purposes of this action only. Except as otherwise admitted, the allegations are denied as stated.

16. On information and belief, Avadel Legacy Pharmaceuticals, LLC is subject to personal jurisdiction in Delaware because Avadel Legacy Pharmaceuticals, LLC 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. Avadel Legacy Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Avadel Legacy Pharmaceuticals, LLC 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 Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel Legacy Pharmaceuticals, LLC is registered to do business in Delaware (business identification number 4886228) 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.

ANSWER: Defendants admit that Avadel Legacy Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Defendants do not dispute that Avadel Legacy Pharmaceuticals, LLC is subject to personal jurisdiction in Delaware for purposes of this action only. Except as otherwise admitted, the allegations are denied as stated.

17. On information and belief, Avadel Management Corporation is subject to personal jurisdiction in Delaware because Avadel Management Corporation 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. Avadel Management Corporation is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Avadel Management Corporation 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 Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel Management Corporation is registered to do business in Delaware (business identification number 6201113) 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.

ANSWER: Defendants admit that Avadel Management Corporation is a corporation organized and existing under the laws of the State of Delaware. Defendants do not dispute that Avadel Management Corporation is subject to personal jurisdiction in Delaware for purposes of this action only. Except as otherwise admitted, the allegations are denied as stated.

18. On information and belief, Avadel CNS Pharmaceuticals LLC is subject to personal jurisdiction in Delaware because Avadel CNS Pharmaceuticals LLC 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. Avadel CNS Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Avadel CNS Pharmaceuticals LLC 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 Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and

belief, Avadel CNS Pharmaceuticals LLC 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.

ANSWER: Admitted.

19. On information and belief, Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC are agents and/or alter egos of one another and work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER: The allegations in Paragraph 19 state legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 19.

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

ANSWER: The allegations in Paragraph 20 state legal conclusions to which no response is required. To the extent a response is required, Defendants do not dispute that they are subject to personal jurisdiction in Delaware for purposes of this action only. Defendants deny the remaining allegations in Paragraph 20.

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

ANSWER: The allegations in Paragraph 21 state legal conclusions to which no response is required. To the extent a response is required, Defendants do not challenge venue for purposes of this action only.

The Patents-In-Suit

22. 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.

ANSWER: Defendants admit that the USPTO issued the '963 patent on May 20, 2014, and that the patent is entitled "Sensitive Drug Distribution System and Method." Defendants admit that Exhibit A appears to be a copy of the '963 patent. Defendants deny that the '963 patent was duly and lawfully issued. Defendants deny the remaining allegations in Paragraph 22.

23. On September 1, 2020, the USPTO duly and lawfully issued the '488 patent entitled, "Controlled Release Dosage Forms for High Dose, Water Soluble and Hygroscopic Drug Substances." A copy of the '488 patent is attached hereto as Exhibit B.

ANSWER: Defendants admit that the USPTO issued the '488 patent on September 1, 2020, and that the patent is entitled "Controlled Release Dosage Forms for High Dose, Water Soluble and Hygroscopic Drug Substances." Defendants admit that Exhibit B appears to be a copy of the '488 patent. Defendants deny that the '488 patent was duly and lawfully issued. Defendants deny the remaining allegations in Paragraph 23.

24. On October 27, 2020, the USPTO duly and lawfully issued the '885 patent entitled, "Controlled Release Dosage Forms for High Dose, Water Soluble and Hygroscopic Drug Substances." A copy of the '885 patent is attached hereto as Exhibit C.

ANSWER: Defendants admit that the USPTO issued the '885 patent on October 27, 2020, and that the patent is entitled "Controlled Release Dosage Forms for High Dose, Water Soluble and Hygroscopic Drug Substances." Defendants admit that Exhibit C appears to be a copy of the '885 patent. Defendants deny that the '885 patent was duly and lawfully issued. Defendants deny the remaining allegations in Paragraph 24.

25. On March 30, 2021, the USPTO duly and lawfully issued the '956 patent entitled, "Controlled Release Dosage Forms for High Dose, Water Soluble and Hygroscopic Drug Substances." A copy of the '956 patent is attached hereto as Exhibit D.

ANSWER: Defendants admit that the USPTO issued the '956 patent on March 30, 2021, and that the patent is entitled "Controlled Release Dosage Forms for High Dose, Water Soluble and Hygroscopic Drug Substances." Defendants admit that Exhibit D appears to be a copy of the '956

patent. Defendants deny that the '956 patent was duly and lawfully issued. Defendants deny the remaining allegations in Paragraph 25.

26. On April 6, 2021, the USPTO duly and lawfully issued the '931 patent entitled, "Controlled Release Dosage Forms for High Dose, Water Soluble and Hygroscopic Drug Substances." A copy of the '931 patent is attached hereto as Exhibit E.

ANSWER: Defendants admit that the USPTO issued the '931 patent on April 6, 2021, and that the patent is entitled "Controlled Release Dosage Forms for High Dose, Water Soluble and Hygroscopic Drug Substances." Defendants admit that Exhibit E appears to be a copy of the '931 patent. Defendants deny that the '931 patent was duly and lawfully issued. Defendants deny the remaining allegations in Paragraph 26.

27. 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.

ANSWER: The allegations in Paragraph 27 state legal conclusions to which no response is required. To the extent a response is required, Defendants refer to the patents-in-suit for their content and deny any allegations inconsistent with those contents. Defendants also deny that the '963 patent is directed to methods of use and administration of sodium oxybate or pharmaceutical composition containing sodium oxbyate. Defendants lack sufficient information to form a belief as to whether Jazz owns the patents-in-suit, but note that Jazz is listed on the face of the patents-in-suit. Defendants deny the remaining allegations in Paragraph 27.

Background

28. 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®. 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®.

ANSWER: On information and belief, Defendants state that Jazz is the purported holder of New Drug Application ("NDA") No. 21-196 for sodium oxybate oral solution. On information and belief, the product that is the subject of NDA No. 21-196 is marketed under the name Xyrem®. On information and belief, the '963 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Xyrem®. Defendants deny that the '963 patent is properly listed in the Orange Book, as addressed in Paragraphs 25 through 31 of the Counterclaims. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations in Paragraph 28, and therefore deny them.

29. Pursuant to its FDA-approved labeling, XYREM® is available only through a restricted distribution program called the XYWAV™ and XYREM® Risk Evaluation and Mitigation Strategy ("REMS") because of the risks of central nervous system depression and abuse, misuse, and diversion.[1]

ANSWER: On information and belief, Defendants state that Xyrem® is available only through the Xywav™ and Xyrem® Risk Evaluation and Mitigation Strategy. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations in Paragraph 29, and therefore deny them.

30. The XYWAV™ and XYREM® REMS is covered by the '963 patent.

ANSWER: The allegations in Paragraph 30 state legal conclusions to which no response is required. To the extent a response is required, Defendants lack sufficient information to form a belief as to the truth of the allegations in Paragraph 30, and therefore deny them.

31. 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 patents-in-suit expire.

[1] XYWAV™ (calcium, magnesium, potassium, and sodium oxybates) oral solution is a product that contains 92% less sodium than XYREM®.

ANSWER: Defendants admit that Avadel filed an NDA pursuant to Section 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the patents-in-suit have not yet expired. Defendants deny the remaining allegations in Paragraph 31.

32. 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.[2]

ANSWER: Defendants admit that on December 16, 2020, Defendant Avadel Pharmaceuticals plc announced Avadel's submission of its NDA to the FDA, and on February 26, 2021, the FDA notified Avadel of formal acceptance of its NDA with an assigned PDUFA target action date of October 15, 2021. Defendants deny the remaining allegations in Paragraph 32.

33. Avadel has identified its Proposed Product using the code name FT218.[3]

ANSWER: Defendants admit that Avadel has identified its Proposed Product using the code name FT218. Defendants deny the remaining allegations in Paragraph 33.

34. Avadel has acknowledged that a REMS will be required for Avadel's Proposed Product.[4]

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[2] 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)

[3] *See id.*

[4] *See id.* at p. 29; *see also* Avadel's May 10, 2021 Q1 2021 Earnings Call Transcript, attached hereto as Exhibit F.

ANSWER: Defendants refer to the document cited in footnote 4 of the Complaint for its content and deny any allegations inconsistent with that content. Defendants deny the remaining allegations in Paragraph 34.

35. Under applicable laws and regulations, the FDA will not approve Avadel's Proposed Product without a REMS.

ANSWER: Defendants lack sufficient information to form a belief as to the truth of the allegations in Paragraph 35, and therefore deny them.

36. Under applicable laws and regulations, the FDA will not approve professional labeling (also called a package insert) for Avadel's Proposed Product without reference to a REMS in that professional labeling.

ANSWER: Defendants lack sufficient information to form a belief as to the truth of the allegations in Paragraph 36, and therefore deny them.

37. The FDA-approved REMS for sodium oxybate are covered by the '963 patent.

ANSWER: The allegations in Paragraph 37 state legal conclusions to which no response is required. To the extent a response is required, Defendants lack sufficient information to form a belief as to the truth of the allegations in Paragraph 37, and therefore deny them.

38. On information and belief, to be approvable by the FDA, the REMS for Avadel's Proposed Product must include protections required in the currently-approved REMS for sodium oxybate products that are covered by the '963 patent.

ANSWER: Denied.

39. On information and belief, the REMS for Avadel's Proposed Product is covered by the '963 patent.

ANSWER: Denied.

40. Avadel has published data comparing the pharmacokinetic properties of Avadel's Proposed Product with twice-nightly sodium oxybate (*i.e.*, XYREM®).[5]

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[5] 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 G.

ANSWER: Defendants admit that the article cited in footnote 5 of the Complaint was published, and that Exhibit G appears to be an accurate copy of the article. Defendants refer to the article cited in footnote 5 for its content and deny any allegations inconsistent with that content. Defendants deny the remaining allegations in Paragraph 40.

41. Avadel owns U.S. Patent No. 10,272,062 ("Avadel's '062 patent") entitled "Modified Release Gamma-Hydroxybutyrate Formulations Having Improved Pharmacokinetics," attached hereto as Exhibit H.

ANSWER: Denied.

42. On information and belief, Avadel's published data concerning the pharmacokinetic properties of Avadel's Proposed Product correspond to the Examples of Avadel's '062 patent.

ANSWER: Defendants refer to any published data concerning the pharmacokinetic properties of FT218 and to the '062 patent for their contents and deny any allegations inconsistent with those contents. Defendants deny the remaining allegations in Paragraph 42.

43. At least Example 1 and Example 1bis of Avadel's '062 patent are covered by Jazz Pharmaceuticals' '488, '885, '956, and '931 patents.

ANSWER: Denied.

44. 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 patents-in-suit.[6] Avadel recently confirmed that is has "accelerated" its launch planning for its Proposed Product.[7]

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218,

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[6] *See* Avadel's 2020 Annual Report at pp. 18, 29, 48 (available at https://www.sec.gov/ix?doc=/Archives/edgar/data/1012477/000101247721000004/avdl-20201231.htm); *see also* Avadel's March 9, 2021 Q4 2020 Earnings Call Transcript, attached hereto as Exhibit I.

[7] *See* Avadel's May 10, 2021 Q1 2021 Earnings Call Transcript, attached hereto as Exhibit F.

a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the patents-in-suit have not yet expired. Defendants refer to the documents cited in footnotes 6 and 7 for their contents and deny any allegations inconsistent with their contents. Defendants deny the remaining allegations in Paragraph 44.

45. On information and belief, Avadel continues to seek approval of its NDA from the FDA and, if approved, intends to commercially have Avadel's Proposed Product manufactured for marketing and sale in the United States.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants deny the remaining allegations in Paragraph 45.

Count I: Infringement of the '963 Patent

46. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants incorporate their responses to the allegations in Paragraphs 1-45 as if fully set forth in this paragraph.

47. Avadel, by the submission of its NDA to the FDA, has indicated that it seeks 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 '963 patent.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the remaining claims of the '963 patent have not yet expired, although several of its claims and all claims of the six related Jazz

patents that purportedly cover Jazz's REMS process were invalidated by the Patent Trial and Appeals Board in *Inter Partes* Reviews. Those invalidity decisions were affirmed by the Federal Circuit. *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347 (Fed. Cir. 2018). Defendants deny the remaining allegations in Paragraph 47.

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

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy on or about December 16, 2020, and that its NDA remains pending. Defendants deny the remaining allegations in Paragraph 48.

49. Avadel's submission of its NDA 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 '963 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Defendants admit that Jazz brought a claim of infringement of the '963 patent under 35 U.S.C. § 271(e)(2)(A). Defendants deny any and all remaining allegations and/or legal conclusions set forth in Paragraph 49, because, *inter alia*, 35 U.S.C. § 271(e)(2)(A) applies solely to NDAs for "a drug claimed in a patent or the use of which is claimed in a patent." The '963 patent covers neither a drug nor a method of using a drug.

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

ANSWER: Defendants admit that there is an actual case or controversy between Jazz and Avadel but deny that Jazz's allegations are valid or sustainable. Defendants deny the remaining allegations in Paragraph 50.

51. 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 '963 patent.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the remaining claims of the '963 patent have not yet expired. Defendants deny the remaining allegations in Paragraph 51.

52. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will infringe one or more claims of the '963 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.

ANSWER: Denied.

53. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will induce infringement of one or more claims of the '963 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, upon FDA approval of Avadel's NDA, Avadel will encourage acts of direct infringement with knowledge of the '963 patent and knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the '963 patent.

ANSWER: Denied.

54. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will contributorily infringe one or more claims of the '963 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 '963 patent and that there is no substantial non-infringing use for Avadel's Proposed Product.

ANSWER: Denied.

55. Plaintiff will be substantially and irreparably damaged and harmed if Avadel's infringement of the '963 patent is not enjoined.

ANSWER: Denied.

56. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Avadel's Proposed Product prior to expiration of the '963 patent by Avadel will constitute direct infringement, induced infringement, and/or contributory infringement of the '963 patent.

ANSWER: Denied.

57. Plaintiff does not have an adequate remedy at law.

ANSWER: Denied.

58. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count II: The Infringement of the '488 Patent

59. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants incorporate their responses to the allegations in Paragraphs 1-58 as if fully set forth in this paragraph.

60. Avadel, by the submission of its NDA to the FDA, has indicated that it seeks 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 '488 patent.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the '488 patent has not yet expired. Defendants deny the remaining allegations in Paragraph 60.

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

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness

and cataplexy in adults with narcolepsy on or about December 16, 2020. Defendants deny the remaining allegations in Paragraph 61.

62. Avadel's submission of its NDA 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 '488 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Defendants admit that Jazz brought a claim under 35 U.S.C. § 271(e)(2)(A). Defendants deny any and all remaining allegations and/or legal conclusions set forth in Paragraph 62.

63. There is a justiciable controversy between the parties hereto as to the infringement of the '488 patent.

ANSWER: Defendants admit that there is an actual case or controversy between Jazz and Avadel but deny that Jazz's allegations are valid or sustainable. Defendants deny the remaining allegations in Paragraph 63.

64. 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 '488 patent.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the '488 patent has not yet expired. Defendants deny the remaining allegations in Paragraph 64.

65. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will infringe one or more claims of the '488 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.

ANSWER: Denied.

66. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will induce infringement of one or more claims of the '488 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, upon FDA approval of Avadel's NDA, Avadel will encourage acts of direct infringement with knowledge of the '488 patent and knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the '488 patent.

ANSWER: Denied.

67. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will contributorily infringe one or more claims of the '488 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 '488 patent and that there is no substantial non-infringing use for Avadel's Proposed Product.

ANSWER: Denied.

68. Plaintiff will be substantially and irreparably damaged and harmed if Avadel's infringement of the '488 patent is not enjoined.

ANSWER: Denied.

69. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Avadel's Proposed Product prior to expiration of the '488 patent by Avadel will constitute direct infringement, induced infringement, and/or contributory infringement of the '488 patent.

ANSWER: Denied.

70. Plaintiff does not have an adequate remedy at law.

ANSWER: Denied.

71. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count III: Infringement of the '885 Patent

72. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants incorporate their responses to the allegations in Paragraphs 1-71 as if fully set forth in this paragraph.

73. Avadel, by the submission of its NDA to the FDA, has indicated that it seeks 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 '885 patent.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the '885 patent has not yet expired. Defendants deny the remaining allegations in Paragraph 73.

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

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy on or about December 16, 2020. Defendants deny the remaining allegations in Paragraph 74.

75. Avadel's submission of its NDA 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 '885 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Defendants admit that Jazz brought a claim under 35 U.S.C. § 271(e)(2)(A). Defendants deny any and all remaining allegations and/or legal conclusions set forth in Paragraph 75.

76. There is a justiciable controversy between the parties hereto as to the infringement of the '885 patent.

ANSWER: Defendants admit that there is an actual case or controversy between Jazz and Avadel but deny that Jazz's allegations are valid or sustainable. Defendants deny the remaining allegations in Paragraph 76.

77. 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 '885 patent.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the '885 patent has not yet expired. Defendants deny the remaining allegations in Paragraph 77.

78. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will infringe one or more claims of the '885 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.

ANSWER: Denied.

79. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will induce infringement of one or more claims of the '885 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, upon FDA approval of Avadel's NDA, Avadel will encourage acts of direct infringement with knowledge of the '885 patent and knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the '885 patent.

ANSWER: Denied.

80. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will contributorily infringe one or more claims of the '885 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 '885 patent and that there is no substantial non-infringing use for Avadel's Proposed Product.

ANSWER: Denied.

81. Plaintiff will be substantially and irreparably damaged and harmed if Avadel's infringement of the '885 patent is not enjoined.

ANSWER: Denied.

82. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Avadel's Proposed Product prior to expiration of the '885 patent by Avadel will constitute direct infringement, induced infringement, and/or contributory infringement of the '885 patent.

ANSWER: Denied.

83. Plaintiff does not have an adequate remedy at law.

ANSWER: Denied.

84. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count IV: Infringement of the '956 Patent

85. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants incorporate their responses to the allegations in Paragraphs 1-84 as if fully set forth in this paragraph.

86. Avadel, by the submission of its NDA to the FDA, has indicated that it seeks 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 '956 patent.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the '956 patent has not yet expired. Defendants deny the remaining allegations in Paragraph 86.

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

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness

and cataplexy in adults with narcolepsy on or about December 16, 2020. Defendants deny the remaining allegations in Paragraph 87.

88. Avadel's submission of its NDA 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 '956 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Defendants admit that Jazz brought a claim under 35 U.S.C. § 271(e)(2)(A). Defendants deny any and all remaining allegations and/or legal conclusions set forth in Paragraph 88.

89. There is a justiciable controversy between the parties hereto as to the infringement of the '956 patent.

ANSWER: Defendants admit that there is an actual case or controversy between Jazz and Avadel but deny that Jazz's allegations are valid or sustainable. Defendants deny the remaining allegations in Paragraph 89.

90. 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 '956 patent.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the '956 patent has not yet expired. Defendants deny the remaining allegations in Paragraph 90.

91. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will infringe one or more claims of the '956 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.

ANSWER: Denied.

92. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will induce infringement of one or more claims of the '956 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, upon FDA approval of Avadel's NDA, Avadel will encourage acts of direct infringement with knowledge of the '956 patent and knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the '956 patent.

ANSWER: Denied.

93. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will contributorily infringe one or more claims of the '956 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 '956 patent and that there is no substantial non-infringing use for Avadel's Proposed Product.

ANSWER: Denied.

94. Plaintiff will be substantially and irreparably damaged and harmed if Avadel's infringement of the '956 patent is not enjoined.

ANSWER: Denied.

95. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Avadel's Proposed Product prior to expiration of the '956 patent by Avadel will constitute direct infringement, induced infringement, and/or contributory infringement of the '956 patent.

ANSWER: Denied.

96. Plaintiff does not have an adequate remedy at law.

ANSWER: Denied.

97. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count V: Infringement of the '931 Patent

98. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants incorporate their responses to the allegations in Paragraphs 1-97 as if fully set forth in this paragraph.

99. Avadel, by the submission of its NDA to the FDA, has indicated that it seeks 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 '931 patent.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the '931 patent has not yet expired. Defendants deny the remaining allegations in Paragraph 99.

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

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy on or about December 16, 2020. Defendants deny the remaining allegations in Paragraph 100.

101. Avadel's submission of its NDA 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 '931 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Defendants admit that Jazz brought a claim under 35 U.S.C. § 271(e)(2)(A). Defendants deny any and all remaining allegations and/or legal conclusions set forth in Paragraph 101.

102. There is a justiciable controversy between the parties hereto as to the infringement of the '931 patent.

ANSWER: Defendants admit that there is an actual case or controversy between Jazz and Avadel but deny that Jazz's allegations are valid or sustainable. Defendants deny the remaining allegations in Paragraph 102.

103. 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 '931 patent.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the '931 patent has not yet expired. Defendants deny the remaining allegations in Paragraph 103.

104. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will infringe one or more claims of the '931 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.

ANSWER: Denied.

105. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will induce infringement of one or more claims of the '931 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, upon FDA approval of Avadel's NDA, Avadel will encourage acts of direct infringement with knowledge of the '931 patent and knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the '931 patent.

ANSWER: Denied.

106. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will contributorily infringe one or more claims of the '931 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 '931 patent and that there is no substantial non-infringing use for Avadel's Proposed Product.

ANSWER: Denied.

107. Plaintiff will be substantially and irreparably damaged and harmed if Avadel's infringement of the '931 patent is not enjoined.

ANSWER: Denied.

108. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Avadel's Proposed Product prior to expiration of the '931 patent by Avadel will constitute direct infringement, induced infringement, and/or contributory infringement of the '931 patent.

ANSWER: Denied.

109. Plaintiff does not have an adequate remedy at law.

ANSWER: Denied.

110. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Jazz's Prayer for Relief

WHEREFORE, Plaintiff respectfully requests the following relief:

(A) A Judgment be entered that Avadel has infringed the patents-in-suit by submitting its NDA for its sodium oxybate drug product;

(B) 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 patents-in-suit;

(C) An Order that the effective date of FDA approval of Avadel's NDA for its sodium oxybate drug product 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 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 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 Avadel, its officers, agents, attorneys and employees, and those acting in privity and/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, sale, or offer for sale, and/or importation into the United States of Avadel's Proposed Product will directly infringe, induce, and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Avadel has committed any acts with respect to the compositions or 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 Avadel engages in the commercial manufacture, use, sale, or offer for sale, or importation into the United States of Avadel'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.

ANSWER: Paragraphs (A)-(K) set forth Jazz's prayer for relief to which no response is required. To the extent that responses to these paragraphs are required, Defendants deny any allegations set forth therein and deny that Jazz is entitled to any relief, including a permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) as, *inter alia*, this action does not implicate that statute, the '963 patent was not appropriately listed in the Orange Book, and Jazz otherwise would not be entitled to relief under said provision.

DEFENSES

Subject to the responses above, upon information and belief, Defendants allege and assert at least the following defenses in response to Jazz's allegations, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are named herein. In addition to the defenses described below, subject to the responses above, Defendants specifically reserve all rights to allege additional defenses that are not required to be pleaded or that become known through the course of discovery.

FIRST DEFENSE
(Non-Infringement)

1. Defendants have not infringed, do not directly infringe, and upon approval of the NDA for FT218, will not infringe any valid, enforceable, asserted claim of the ’963 patent, either literally or under the doctrine of equivalents, or under any theory of infringement.

2. Defendants have not infringed, do not directly infringe, and upon approval of the NDA for FT218, will not infringe any valid, enforceable, asserted claim of the ’488 patent, either literally or under the doctrine of equivalents, or under any theory of infringement.

3. Defendants have not infringed, do not directly infringe, and upon approval of the NDA for FT218, will not infringe any valid, enforceable, asserted claim of the ’885 patent, either literally or under the doctrine of equivalents, or under any theory of infringement.

4. Defendants have not infringed, do not directly infringe, and upon approval of the NDA for FT218, will not infringe any valid, enforceable, asserted claim of the ’956 patent, either literally or under the doctrine of equivalents, or under any theory of infringement.

5. Defendants have not infringed, do not directly infringe, and upon approval of the NDA for FT218, will not infringe any valid, enforceable, asserted claim of the ’931 patent, either literally or under the doctrine of equivalents, or under any theory of infringement.

SECOND DEFENSE
(Invalidity)

6. Each of the asserted claims of the ’963 patent is invalid for failure to comply with one or more conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

7. Each of the asserted claims of the ’488 patent is invalid for failure to comply with one or more conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

8. Each of the asserted claims of the ’885 patent is invalid for failure to comply with one or more conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

9. Each of the asserted claims of the ’956 patent is invalid for failure to comply with one or more conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

10. Each of the asserted claims of the ’931 patent is invalid for failure to comply with one or more conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

THIRD DEFENSE
(Prosecution History Disclaimer and Estoppel)

11. Jazz is barred, based on statements, representations, and admissions made during prosecution of the patent applications resulting in the asserted patents or related patent applications, from asserting any interpretation of any valid, enforceable claim of the asserted patents that would be broad enough to cover any accused product or method alleged to infringe the asserted patents, either literally or by application of the doctrine of equivalents, or under any theory of infringement.

FOURTH DEFENSE
(Failure to State A Claim Upon Which Relief Can Be Granted)

12. Jazz’s Complaint fails to state a claim upon which relief can be granted.

FIFTH DEFENSE
(Patent Misuse)

13. By its conduct, Jazz has engaged in patent misuse by asserting infringement claims it knows or should have known are meritless, including infringement of claims that are improperly listed in the Orange Book, as evidenced below in Paragraphs 25 through 31 of the Counterclaims. Jazz’s patent misuse renders the ’963 patent unenforceable.

SIXTH DEFENSE
(Equitable Defenses)

14. Jazz’s attempted enforcement of the asserted patents against Defendants is barred by one or more of the equitable doctrines of estoppel, acquiescence, and/or waiver.

SEVENTH DEFENSE
(No Willfulness)

15. Jazz is barred from seeking and/or obtaining a finding of willfulness or receiving enhanced damages because Jazz has failed to allege Defendants engaged in any willful infringement or reprehensible conduct and Defendants have engaged in no such conduct, which is a prerequisite for a finding of willfulness and an award of enhanced damages.

EIGHTH DEFENSE
(Attorneys' Fees)

16. Jazz has failed to state facts sufficient to support an award of attorneys' fees.

NINTH DEFENSE
(Limitations on Costs)

17. To the extent that Jazz prevails on any of its allegations, its demand for costs is limited or barred pursuant to 35 U.S.C. § 288 because claims of the asserted patents are invalid.

TENTH DEFENSE
(Improper Hatch-Waxman Suit)

18. Jazz's infringement claims brought pursuant to the Hatch-Waxman Statute are improper, including because the '963 patent is improperly listed in the Orange Book, and Jazz is not entitled to any relief under that Statute, including a permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B).

ELEVENTH DEFENSE
(Other Defenses)

19. Defendants reserve the right to supplement or amend this Answer and reserve all defenses set out in Rule 8(c) of the Federal Rules of Civil Procedure, the Patent Laws of the United States, and any other defenses, at law or in equity, which become applicable during the course of discovery or otherwise in the course of litigation.

AVADEL'S COUNTERCLAIMS

1. Avadel's Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

2. The Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338.

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

4. Counterclaim-Plaintiff Avadel CNS Pharmaceuticals, LLC ("Avadel") is a limited liability company organized and existing under the laws of the State of Delaware and has its principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005.

5. Upon information and belief, Counterclaim-Defendant Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 3170 Porter Drive, Palo Alto, California 94304.

Preliminary Statement

6. Avadel Ireland owns six United States patents that cover Avadel's innovative product FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. One of those patents, U.S. Patent No. 10,272,062 (the "'062 patent"), entitled "Modified Release Gamma-Hydroxybutyrate Formulations Having Improved Pharmacokinetics," was filed on July 21, 2017 and issued on April 30, 2019.

7. On information and belief, Jazz was aware of the disclosures in the '062 patent since at least January 25, 2018, when the application that ultimately issued as the '062 patent (the "'062 application") was first published.

8. On information and belief, Jazz presumed that at least Example 1 and Example 1bis of the '062 application disclose the formulation of FT218, Avadel's once-nightly sodium oxybate formulation for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Indeed, Jazz's complaint in the instant action makes such an assumption.

9. The '062 application disclosed modified release formulations of gamma-hydroxybutyrate ("GHB" with sodium oxybate being its sodium salt) containing methacrylic acid-methyl methacrylate co-polymers, with certain dissolution profiles when tested in deionized water using USP apparatus 2 and where the dissolution medium was maintained at 37°C ± 0.5° C with the rotating paddle speed fixed at 50 rpm.

10. At the time that the '062 application was published on January 25, 2018, Jazz had not filed any of the patent applications that ultimately issued as Jazz's asserted '488, '885, '956, and '931 patents, and was instead prosecuting the parent application to those patents, U.S. Application No. 13/071369 (the "Jazz '369 application"). The then-pending claims of the Jazz '369 application were directed to a "controlled release dosage form for oral administration" including a "compressed tablet controlled release core," comprising at least one polymer comprising ethylcellulose, at least one polymeric "pore former," and also recited "providing a time dependent release" measuring release of the drug from time of administration. *See, e.g.*, Jazz '369 application File History, October 4, 2017 Response to Final Office Action at claim 1. One dependent claim recited that the "at least one polymeric pore-former is at least one of a polyethylene glycol, poloxamer, polyvinyl alcohol, copovidone, povidone, a water soluble sugar, a water soluble organic acid, such as carboxylic acids and their salts, and a hydroxyalkyl cellulose selected from hydroxyethyl cellulose, hydroxypropyl methylcellulose, and hydroxypropyl cellulose." *See* Jazz '369 application File History, October 4, 2017 Response to Final Office

Action at claim 16. The Jazz '369 application claims therefore corresponded to the substance of the specification, which disclosed controlled release dosage forms containing a compressed tablet controlled release core, ethylcellulose, and hydroxypropyl cellulose or poloxamer. *See, e.g.*, Jazz '369 application at Examples 1-13.

11. Claim 1 of the Jazz '369 application was originally directed to "a controlled release dosage form for oral administration," but the applicant narrowed claim 1 first to a "compressed tablet" and later to include a "compressed tablet controlled release core," in response to rejections finding that claim 1 was obvious over a prior art patent application to Liang *et al*. *See* Jazz '369 application File History, May 28, 2013 Response to Office Action at claim 1; January 27, 2014 response to Office Action at claim 1. These narrowing amendments conformed the claims to the disclosure of the Jazz '369 application, which was limited to a compressed tablet dosage form. Further, the Jazz '369 application had no claims or teachings of dissolution testing or the release profiles resulting from such testing of formulations containing methacrylic acid-methyl methacrylate co-polymers in deionized water using apparatus 2 at a temperature of 37°C and a paddle speed of 50 rpm, as described in the '062 application. After the '062 application was published, Jazz let its '369 application become abandoned on November 2, 2018.

12. Jazz did not file the application that ultimately led to the issuance of the '488 patent until July 2, 2018 – ***after*** the '062 application was published. The '488 patent was filed and characterized as a continuation of the Jazz '369 application. Notably, Jazz canceled all 108 original claims that generally recited the four components described *supra* – namely a "compressed tablet" controlled release dosage form, comprising at least one polymer comprising ethylcellulose, at least one polymeric "pore former," and reciting "providing a time dependent release" measuring release of the drug from time of administration. In stark contrast to its prior set of claims, Jazz

deleted each of those four attributes, and replaced them with claims directed to a generic formulation (rather than a compressed tablet) comprising specifically methacrylic acid-methyl methacrylate co-polymers (rather than one polymer comprising ethylcellulose and at least one polymeric "pore former"), and recited a specific dissolution profile defined by tests performed "in a dissolution apparatus 2 in deionized water at a temperature of 37°C and a paddle speed of 50 rpm" (rather than reciting attributes following administration).

13. On information and belief, Jazz drafted the claims that ultimately issued as the '488 patent based not on any commensurate disclosure of its underlying application, but solely in view of the disclosures set forth in the '062 application. The '488 patent specification does not disclose dissolution testing or the release profile resulting from such testing of formulations containing methacrylic acid-methyl methacrylate co-polymers in deionized water using apparatus 2 at a temperature of 37°C and a paddle speed of 50 rpm. As such, the '488 patent claims as filed and issued are neither described nor supported by its specification as, on information and belief, the claims were instead solely based on Avadel Ireland's inventive work disclosed in at least the '062 Application.

14. Jazz filed the application that ultimately issued as the '885 patent on June 30, 2020 as a continuation of at least the '488 patent. Like with the '488 patent, on information and belief, the claims of the '885 patent were written based on the disclosures in the '062 application. The '885 patent was filed and has issued with claims to formulations comprising methacrylic acid-methyl methacrylate co-polymers and a specific dissolution profile defined by tests performed "in a dissolution apparatus 2 in deionized water at a temperature of 37°C and a paddle speed of 50 rpm." For the same reasons as above, the '885 patent claims are neither described nor supported

by its patent specification, as the claims were written based solely on Avadel Ireland's inventive work disclosed in at least the '062 application.

15. Jazz filed the application that ultimately issued as the '956 patent on September 4, 2020 as a continuation of at least the '885 patent. As with the '885 patent, the '956 patent was filed and has issued with claims to formulations comprising methacrylic acid-methyl methacrylate co-polymers and a specific dissolution profile defined by tests performed "in a dissolution apparatus 2 in deionized water at a temperature of 37°C and a paddle speed of 50 rpm." For the same reasons as above, the '956 patent claims are neither described nor supported by its patent specification, as the claims were written solely based on Avadel Ireland's inventive work disclosed in at least the '062 application.

16. Jazz filed the application that ultimately issued as the '931 patent on September 4, 2020 as a continuation of at least the '885 patent. As with the '885 patent, the '931 patent was filed and has issued with claims to formulations comprising methacrylic acid-methyl methacrylate co-polymers and a specific dissolution profile defined by tests performed "in a dissolution apparatus 2 in deionized water at a temperature of 37°C and a paddle speed of 50 rpm." For the same reasons as above, the '931 patent claims are neither described nor supported by its patent specification, as the claims were written solely based on Avadel Ireland's inventive work disclosed in at least the '062 application.

Count I: Declaratory Judgment of Non-Infringement of the '963 Patent

17. Avadel incorporates by reference the allegations made in Avadel's Defenses and in the preceding paragraphs of the Counterclaims above.

18. An actual controversy exists between Avadel and Jazz over the alleged infringement of at least one claim of the '963 patent. Jazz holds itself out as the owner of the '963 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel's NDA infringes

at least claim 1 of the ’963 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel’s Proposed Product in the United States infringes at least claim 1 of the ’963 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

19. The submission of Avadel’s NDA does not infringe the ’963 patent in violation of 35 U.S.C. § 271(e), either literally or under the doctrine of equivalents. The making, using, offering to sell, selling, and/or importation of Avadel’s Proposed Product in the United States would not infringe any valid claim of the ’963 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), either literally or under the doctrine of equivalents. Avadel hereby seeks a declaration that the submission of Avadel’s NDA, and the making, using, offering to sell, selling, and/or importation of Avadel’s Proposed Product in the United States does not infringe and/or will not infringe any valid claim of the ’963 patent.

20. Avadel has not infringed, is not infringing, and will not infringe any valid claim of the ’963 patent, directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner. A judicial declaration is necessary and appropriate so that Avadel may ascertain its rights regarding the ’963 patent.

Count II: Declaratory Judgment of Invalidity of the ’963 Patent

21. Avadel incorporates by reference the allegations made in Avadel’s Defenses and in the preceding paragraphs of the Counterclaims above.

22. An actual controversy exists between Avadel and Jazz over the invalidity of the ’963 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel’s NDA infringes at least claim 1 of the ’963 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel’s Proposed Product

in the United States infringes at least claim 1 of the ’963 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

23. All claims of the ’963 patent are invalid because they fail to comply with one or more requirements of the United States Code Title 35, including, without limitation, one or more requirements of 35 U.S.C. §§ 102, 103, and/or 112. Avadel expressly reserves all rights to identify and assert additional invalidity positions in this case.

24. Avadel hereby seeks a declaration that the claims of the ’963 patent are invalid.

Count III: Declaratory Judgment Requiring Delisting the ’963 Patent

25. Avadel incorporates by reference the allegations made in Avadel’s Defenses and in the preceding paragraphs of the Counterclaims above.

26. An actual controversy exists between Avadel and Jazz over the listing of the ’963 patent in the Orange Book.

27. Under 21 C.F.R. § 314.53(c), only patents claiming a drug product, drug substance, or method of using the drug may be listed in the Orange Book.

28. The ’963 patent only includes claims to a “computer-implemented system for treatment of a narcoleptic patient with a prescription drug . . . ,” which are neither method claims nor claims to a drug product or drug substance.

29. The FDA requires patent holders who list patents in the Orange Book to submit a Use Code, which is a code to designate a method patent that covers the approved indication or use of a drug product. Jazz characterized the “computer system” claimed in the ’963 Patent according to the use code “U-1110: METHOD OF TREATING A PATIENT WITH A PRESCRIPTION DRUG USING A COMPUTER DATABASE IN A COMPUTER SYSTEM FOR DISTRIBUTION.”

30. The ’963 patent does not claim a method of using the approved drug product as required by 21 C.F.R. § 314.53(c) and thus should be removed from the Orange Book.

31. Avadel hereby seeks a declaration pursuant to 21 U.S.C. § 355(c)(3)(D)(ii)(I) ordering Jazz to remove the ’963 patent from the Orange Book.

Count IV: Declaratory Judgment of Non-Infringement of the ’488 Patent

32. Avadel incorporates by reference the allegations made in Avadel’s Defenses and in the preceding paragraphs of the Counterclaims above.

33. An actual controversy exists between Avadel and Jazz over the alleged infringement of at least one claim of the ’488 patent. Jazz holds itself out as the owner of the ’488 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel’s NDA infringes at least claim 1 of the ’488 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel’s Proposed Product in the United States infringes at least claim 1 of the ’488 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

34. The submission of Avadel’s NDA does not infringe the ’488 patent in violation of 35 U.S.C. § 271(e), either literally or under the doctrine of equivalents. The making, using, offering to sell, selling, and/or importation of Avadel’s Proposed Product in the United States would not infringe any valid claim of the ’488 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), either literally or under the doctrine of equivalents. In light of various statements made by the Jazz applicants during the course of prosecution, the Avadel FT218 product does not infringe and cannot infringe any valid claim of the ’488 patent. Avadel hereby seeks a declaration that the submission of Avadel’s NDA, and the making, using, offering to sell, selling, and/or importation of Avadel’s Proposed Product in the United States does not infringe and/or will not infringe any valid claim of the ’488 patent.

35. Avadel has not infringed, is not infringing, and will not infringe any valid claim of the '488 patent, directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner. A judicial declaration is necessary and appropriate so that Avadel may ascertain its rights regarding the '488 patent.

Count V: Declaratory Judgment of Invalidity of the '488 Patent

36. Avadel incorporates by reference the allegations made in Avadel's Defenses and in the preceding paragraphs of the Counterclaims above.

37. An actual controversy exists between Avadel and Jazz over the invalidity of the '488 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel's NDA infringes at least claim 1 of the '488 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States infringes at least claim 1 of the '488 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

38. In light of various statements made by the Jazz applicants during the course of prosecution, the Avadel FT218 product does not infringe and cannot infringe any valid claim of the '488 patent. To the extent otherwise, all of the claims of the '488 patent are invalid because they fail to comply with one or more requirements of the United States Code Title 35, including, without limitation, one or more requirements of 35 U.S.C. §§ 102, 103, and/or 112. For example, as set forth in Paragraphs 6 through 13 of the Counterclaims, the claims of the '488 patent are invalid for at least derivation pursuant to pre-AIA 35 U.S.C. § 102(f) and/or lack of written description under 35 U.S.C. § 112 because the claims as filed are neither described nor supported by the specification.

39. Alternatively, because the claims of the '488 patent are unsupported by the written description, they are not entitled to claim priority to the Jazz '369 application and are subject to

the provisions of the AIA. Under post-AIA law, the claims of the '488 patent are invalid under 35 U.S.C. § 102 over the '062 application, because Avadel Ireland effectively filed a patent application with the pertinent subject matter before the earliest date to which the '488 patent can claim priority. Avadel expressly reserves all rights to identify and assert additional invalidity positions in this case.

40. Avadel hereby seeks a declaration that the claims of the '488 patent are invalid.

Count VI: Declaratory Judgment of Non-Infringement of the '885 Patent

41. Avadel incorporates by reference the allegations made in Avadel's Defenses and in the preceding paragraphs of the Counterclaims above.

42. An actual controversy exists between Avadel and Jazz over the alleged infringement of at least one claim of the '885 patent. Jazz holds itself out as the owner of the '885 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel's NDA infringes at least claim 1 of the '885 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States infringes at least claim 1 of the '885 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

43. The submission of Avadel's NDA does not infringe the '885 patent in violation of 35 U.S.C. § 271(e), either literally or under the doctrine of equivalents. The making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States would not infringe any valid claim of the '885 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), either literally or under the doctrine of equivalents. In light of various statements made by the Jazz applicants during the course of prosecution, the Avadel FT218 product does not infringe and cannot infringe any valid claim of the '885 patent. Avadel hereby seeks a declaration that the submission of Avadel's NDA, and the making, using, offering to sell, selling, and/or

importation of Avadel's Proposed Product in the United States does not infringe and/or will not infringe any valid claim of the '885 patent.

44. Avadel has not infringed, is not infringing, and will not infringe any valid claim of the '885 patent, directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner. A judicial declaration is necessary and appropriate so that Avadel may ascertain its rights regarding the '885 patent.

Count VII: Declaratory Judgment of Invalidity of the '885 Patent

45. Avadel incorporates by reference the allegations made in Avadel's Defenses and in the preceding paragraphs of the Counterclaims above.

46. An actual controversy exists between Avadel and Jazz over the invalidity of the '885 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel's NDA infringes at least claim 1 of the '885 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States infringes at least claim 1 of the '885 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

47. In light of various statements made by the Jazz applicants during the course of prosecution, the Avadel FT218 product does not infringe and cannot infringe any valid claim of the '885 patent. To the extent otherwise, all of the claims of the '885 patent are invalid because they fail to comply with one or more requirements of the United States Code Title 35, including, without limitation, one or more requirements of 35 U.S.C. §§ 102, 103, and/or 112. For example, as set forth in Paragraphs 6 through 12 and 14 of the Counterclaims, the claims of the '885 patent are invalid for at least derivation pursuant to pre-AIA 35 U.S.C. § 102(f) and/or lack of written description under 35 U.S.C. § 112 because the claims as filed are neither described nor supported by the specification.

48. Alternatively, because the claims of the ’885 patent are unsupported by the written description, they are not entitled to claim priority to the Jazz ’369 application and are subject to the provisions of the AIA. Under post-AIA law, the claims of the ’885 patent are invalid under 35 U.S.C. § 102 over the ’062 application, because Avadel Ireland effectively filed a patent application with the pertinent subject matter before the earliest date to which the ’885 patent can claim priority. Avadel expressly reserves all rights to identify and assert additional invalidity positions in this case.

49. Avadel hereby seeks a declaration that the claims of the ’885 patent are invalid.

Count VIII: Declaratory Judgment of Non-Infringement of the ’956 Patent

50. Avadel incorporates by reference the allegations made in Avadel’s Defenses and in the preceding paragraphs of the Counterclaims above.

51. An actual controversy exists between Avadel and Jazz over the alleged infringement of at least one claim of the ’956 patent. Jazz holds itself out as the owner of the ’956 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel’s NDA infringes at least claim 1 of the ’956 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel’s Proposed Product in the United States infringes at least claim 1 of the ’956 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

52. The submission of Avadel’s NDA does not infringe the ’956 patent in violation of 35 U.S.C. § 271(e), either literally or under the doctrine of equivalents. The making, using, offering to sell, selling, and/or importation of Avadel’s Proposed Product in the United States would not infringe any valid claim of the ’956 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), either literally or under the doctrine of equivalents. In light of various statements made by the Jazz applicants during the course of prosecution, the Avadel FT218 product does not

infringe and cannot infringe any valid claim of the ’956 patent. Avadel hereby seeks a declaration that the submission of Avadel’s NDA, and the making, using, offering to sell, selling, and/or importation of Avadel’s Proposed Product in the United States does not infringe and/or will not infringe any valid claim of the ’956 patent.

53. Avadel has not infringed, is not infringing, and will not infringe any valid claim of the ’956 patent, directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner. A judicial declaration is necessary and appropriate so that Avadel may ascertain its rights regarding the ’956 patent.

Count IX: Declaratory Judgment of Invalidity of the ’956 Patent

54. Avadel incorporates by reference the allegations made in Avadel’s Defenses and in the preceding paragraphs of the Counterclaims above.

55. An actual controversy exists between Avadel and Jazz over the invalidity of the ’956 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel’s NDA infringes at least claim 1 of the ’956 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel’s Proposed Product in the United States infringes at least claim 1 of the ’956 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

56. In light of various statements made by the Jazz applicants during the course of prosecution, the Avadel FT218 product does not infringe and cannot infringe any valid claim of the ’956 patent. To the extent otherwise, all of the claims of the ’956 patent are invalid because they fail to comply with one or more requirements of the United States Code Title 35, including, without limitation, one or more requirements of 35 U.S.C. §§ 102, 103, and/or 112. For example, as set forth in Paragraphs 6 through 12 and 15 of the Counterclaims, the claims of the ’956 patent are invalid for at least derivation pursuant to pre-AIA 35 U.S.C. § 102(f) and/or lack of written

description under 35 U.S.C. § 112 because the claims as filed are neither described nor supported by the specification.

57. Alternatively, because the claims of the ’956 patent are unsupported by the written description, they are not entitled to claim priority to the Jazz ’369 application and are subject to the provisions of the AIA. Under post-AIA law, the claims of the ’956 patent are invalid under 35 U.S.C. § 102 over the ’062 application, because Avadel Ireland effectively filed a patent application with the pertinent subject matter before the earliest date to which the ’956 patent can claim priority. Avadel expressly reserves all rights to identify and assert additional invalidity positions in this case.

58. Avadel hereby seeks a declaration that the claims of the ’956 patent are invalid.

Count X: Declaratory Judgment of Non-Infringement of the ’931 Patent

59. Avadel incorporates by reference the allegations made in Avadel’s Defenses and in the preceding paragraphs of the Counterclaims above.

60. An actual controversy exists between Avadel and Jazz over the alleged infringement of at least one claim of the ’931 patent. Jazz holds itself out as the owner of the ’931 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel’s NDA infringes at least claim 1 of the ’931 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel’s Proposed Product in the United States infringes at least claim 1 of the ’931 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

61. The submission of Avadel’s NDA does not infringe the ’931 patent in violation of 35 U.S.C. § 271(e), either literally or under the doctrine of equivalents. The making, using, offering to sell, selling, and/or importation of Avadel’s Proposed Product in the United States would not infringe any valid claim of the ’931 patent in violation of 35 U.S.C. §§ 271(a), 271(b),

and/or 271(c), either literally or under the doctrine of equivalents. In light of various statements made by the Jazz applicants during the course of prosecution, the Avadel FT218 product does not infringe and cannot infringe any valid claim of the '931 patent. Avadel hereby seeks a declaration that the submission of Avadel's NDA, and the making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States does not infringe and/or will not infringe any valid claim of the '931 patent.

62. Avadel has not infringed, is not infringing, and will not infringe any valid claim of the '931 patent, directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner. A judicial declaration is necessary and appropriate so that Avadel may ascertain its rights regarding the '931 patent.

Count XI: Declaratory Judgment of Invalidity of the '931 Patent

63. Avadel incorporates by reference the allegations made in Avadel's Defenses and in the preceding paragraphs of the Counterclaims above.

64. An actual controversy exists between Avadel and Jazz over the invalidity of the '931 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel's NDA infringes at least claim 1 of the '931 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States infringes at least claim 1 of the '931 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

65. In light of various statements made by the Jazz applicants during the course of prosecution, the Avadel FT218 product does not infringe and cannot infringe any valid claim of the '931 patent. To the extent otherwise, all of the claims of the '931 patent are invalid because they fail to comply with one or more requirements of the United States Code Title 35, including, without limitation, one or more requirements of 35 U.S.C. §§ 102, 103, and/or 112. For example,

as set forth in Paragraphs 6 through 12 and 16 of the Counterclaims, the claims of the '931 patent are invalid for at least derivation pursuant to pre-AIA 35 U.S.C. § 102(f) and/or lack of written description under 35 U.S.C. § 112 because the claims as filed are neither described nor supported by the specification.

66. Alternatively, because the claims of the '931 patent are unsupported by the written description, they are not entitled to claim priority to the Jazz '369 application and are subject to the provisions of the AIA. Under post-AIA law, the claims of the '931 patent are invalid under 35 U.S.C. § 102 over the '062 application, because Avadel Ireland effectively filed a patent application with the pertinent subject matter before the earliest date to which the '931 patent can claim priority. Avadel expressly reserves all rights to identify and assert additional invalidity positions in this case.

67. Avadel hereby seeks a declaration that the claims of the '931 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Avadel requests the following relief:

A. That the Court enter judgment against Jazz and in favor of Avadel on the claims set forth in Jazz's Complaint and that each claim be dismissed with prejudice;

B. That the Court enter judgment that Avadel does not infringe and/or will not infringe any valid claims of the asserted patents in violation of 35 U.S.C. §§ 271(a), 271(b), 271(c), and/or 271(e), or any other theory of infringement;

C. That the Court enter judgment that the asserted patents are invalid;

D. That the Court determine that pursuant to 35 U.S.C. § 285, Jazz's conduct in commencing and pursing this action renders this an exceptional case and award Avadel its reasonable attorneys' fees and its costs and disbursements in this action; and

E. That the Court grant Avadel such other and further relief, in law or equity, as the Court deems just and proper.

Dated: June 3, 2021

MCCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Counsel for Defendants

Of Counsel:

Kenneth G. Schuler
Marc N. Zubick
Alex Grabowski
Sarah W. Wang
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
(312) 876-7700
kenneth.schuler@lw.com
marc.zubick@lw.com
alex.grabowski@lw.com
sarah.wang@lw.com