IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-691-GBW **JURY TRIAL DEMANDED**

ANSWER TO AMENDED 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 received approval of a New Drug Application ("NDA") from the FDA for its branded medication, FT218 (commercially known as LUMRYZ™), 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 was 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 CNS Pharmaceuticals, LLC denies that it infringes, has infringed, or will infringe any valid claim of the asserted patents, denies that there is any legitimate basis for the lawsuit brought by Jazz, denies that Jazz is entitled to any relief, and denies the allegations and characterizations in Jazz's Amended Complaint unless expressly admitted as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Avadel's filing of a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a sodium oxybate drug product prior to the expiration of United States Patent Nos. 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"), and the FDA's subsequent approval thereof.

ANSWER: Defendant admits that the Amended Complaint purports to allege an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, et seq. involving United States Patent Nos. 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. Defendant admits 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. Defendant admits that on May 1, 2023 Avadel received final approval of its NDA from the FDA. Defendant admits that the patents-in-suit have not yet expired. Defendant denies that the Amended 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: Defendant lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies them.

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

ANSWER: Defendant admits 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. Defendant admits that Avadel CNS Pharmaceuticals, LLC develops, manufactures, markets, imports, offers for sale, and sells pharmaceutical products throughout the United States. Defendant denies the remaining allegations in Paragraph 3.

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

ANSWER: Defendant admits that Avadel CNS Pharmaceuticals, LLC has made, used, offered to sell, and/or sold LUMRYZ™ within the United States. Defendant denies the remaining allegations of Paragraph 4.

Jurisdiction and Venue

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

ANSWER: The allegations in Paragraph 5 state legal conclusions to which no response is required. To the extent a response is required, Defendant does not dispute subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a).

6. On information and belief, Defendant is subject to personal jurisdiction in Delaware because Defendant has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Defendant is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Defendant manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Defendant is registered to do business in Delaware (business identification number 7734658) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

ANSWER: Admitted.

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

ANSWER: The allegations in Paragraph 7 state legal conclusions to which no response is required. To the extent a response is required, Defendant does not dispute that they are subject to personal jurisdiction in Delaware for purposes of this action only. Defendant denies the remaining allegations in Paragraph 7.

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

ANSWER: The allegations in Paragraph 8 state legal conclusions to which no response is required. To the extent a response is required, Defendant does not challenge venue for purposes of this action only.

The Patents-In-Suit

9. On September 1, 2020, the United States Patent and Trademark Office ("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 A.

ANSWER: Defendant admits 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." Defendant admits that Exhibit A appears to be a copy of the '488 patent. Defendant denies that the '488 patent was duly and lawfully issued. Defendant denies the remaining allegations in Paragraph 9.

10. 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 B.

ANSWER: Defendant admits 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." Defendant admits that Exhibit B appears to be a copy of the '885 patent. Defendant denies that the '885 patent was duly and lawfully issued. Defendant denies the remaining allegations in Paragraph 10.

11. 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 C.

ANSWER: Defendant admits 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 C appears to be a copy of the '956 patent. Defendant denies that the '956 patent was duly and lawfully issued. Defendant denies the remaining allegations in Paragraph 11.

12. 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 D

ANSWER: Defendant admits 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." Defendant admits that Exhibit D appears to be a copy of the '931 patent. Defendant denies that the '931 patent was duly and lawfully issued. Defendant denies the remaining allegations in Paragraph 12.

13. 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 13 state legal conclusions to which no response is required. To the extent a response is required, Defendant refers to the patents-in-suit for their content and deny any allegations inconsistent with those contents. Defendant lacks 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. Defendant denies the remaining allegations in Paragraph 13.

Background

14. 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®.

ANSWER: On information and belief, Defendant states 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®. Defendant lacks sufficient information to form a belief as to the truth of the remaining allegations in Paragraph 14, and therefore denies them.

Acts Giving Rise to This Suit

15. 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.

ANSWER: Defendant admits 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. Defendant admits that the patents-in-suit have not yet expired. Defendant denies the remaining allegations in Paragraph 15.

16. On December 16, 2020, Avadel announced the submission of its NDA to the FDA. On information and belief, on February 26, 2021, the FDA notified Avadel of formal acceptance of Avadel's NDA with an assigned Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021.[1]

ANSWER: Defendant admits that on December 16, 2020, 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 16.

17. Avadel has identified its Proposed Product using both the code name FT218[2] and the commercial name LUMRYZ™.

ANSWER: Admitted.

18. Avadel has published data comparing the pharmacokinetic properties of Avadel's Proposed Product with twice-nightly sodium oxybate (*i.e.*, XYREM®).[3]

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

[2] *See id.*

[3] Seiden, et al., *Pharmacokinetics of FT218, a Once-Nightly Sodium Oxybate Formulation*

ANSWER: Defendant admits that the article cited in footnote 3 of the Amended Complaint was published, and that Exhibit E appears to be an accurate copy of the article. Defendant refers to the article cited in footnote 3 for its content and deny any allegations inconsistent with that content. Defendant denies the remaining allegations in Paragraph 18.

19. 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 F.

ANSWER: Denied.

20. 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: Defendant refers 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. Defendant denies the remaining allegations in Paragraph 20.

21. 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.

22. On information and belief, Avadel has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Avadel's Proposed Product prior to expiration of the patents-in-suit. For example, on information and belief, Avadel received permission from FDA to import into the United States commercially manufactured batches of its Proposed Product.

ANSWER: Defendant admits 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. Defendant admits that it has received permission from FDA to import into the United States batches of FT218 for commercial sale and has engaged in such

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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 E.

importation. Defendant admits that the patents-in-suit have not yet expired. Defendants deny the remaining allegations in Paragraph 22.

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

ANSWER: Admitted.

Count I: Infringement of the '488 Patent

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

ANSWER: Defendant incorporates its responses to the allegations in Paragraphs 1-23 as if fully set forth in this paragraph.

25. Avadel, by the submission of its NDA to the FDA, sought approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel's Proposed Product, prior to the expiration of the '488 patent.

ANSWER: Defendant admits 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. Defendant admits that the '488 patent has not yet expired. Defendant denies the remaining allegations in Paragraph 25.

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

ANSWER: Defendant admits 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. Defendant admits that on May 1, 2023 Avadel received final approval of its NDA from the FDA. Defendant denies the remaining allegations in Paragraph 26.

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

ANSWER: Admitted.

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

ANSWER: Defendant admits that there is an actual case or controversy between Jazz and Avadel but deny that Jazz's allegations are valid or sustainable. Defendant denies the remaining allegations in Paragraph 28.

29. Avadel has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Avadel's Proposed Product prior to the expiration of the '488 patent. For example, on information and belief, Avadel received permission from FDA to import into the United States commercially manufactured batches of its Proposed Product and has imported the product.

ANSWER: Defendant admits 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. Defendant admits that it has received permission from FDA to import into the United States batches of FT218 for commercial sale and has engaged in such importation. Defendant admits that the '488 patent has not yet expired. Defendant denies the remaining allegations in Paragraph 29.

30. Avadel has infringed and 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.

31. Avadel has induced infringement and 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, Avadel has encouraged and 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.

32. Avadel has contributorily infringed and 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.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

36. 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: Infringement of the ’885 Patent

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

ANSWER: Defendant incorporates its responses to the allegations in Paragraphs 1-36 as if fully set forth in this paragraph.

38. Avadel, by the submission of its NDA to the FDA, sought approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel’s Proposed Product, prior to the expiration of the ’885 patent.

ANSWER: Defendant admits 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. Defendant admits that the '885 patent has not yet expired. Defendant denies the remaining allegations in Paragraph 38.

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

ANSWER: Defendant admits 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. Defendant denies the remaining allegations in Paragraph 39.

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

ANSWER: Admitted.

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

ANSWER: Defendant admits that there is an actual case or controversy between Jazz and Avadel but deny that Jazz's allegations are valid or sustainable. Defendant denies the remaining allegations in Paragraph 41.

42. 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. For example, on information and belief, Avadel received permission from FDA to import into the United States commercially manufactured batches of its Proposed Product and has imported the product.

ANSWER: Defendant admits 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. Defendant admits that it has received permission from FDA to

import into the United States batches of FT218 for commercial sale and has engaged in such importation. Defendant admits that the '885 patent has not yet expired. Defendant denies the remaining allegations in Paragraph 42.

43. Avadel has infringed and 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.

44. Avadel has induced infringement and 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, Avadel has encouraged and 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.

45. Avadel has contributorily infringed and 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.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

49. 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 '956 Patent

50. 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 1-49 as if fully set forth in this paragraph.

51. Avadel, by the submission of its NDA to the FDA, sought approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel's Proposed Product, prior to the expiration of the '956 patent.

ANSWER: Defendant admits 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. Defendant admits that the '956 patent has not yet expired. Defendant denies the remaining allegations in Paragraph 51.

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

ANSWER: Defendant admits 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. Defendant denies the remaining allegations in Paragraph 52.

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

ANSWER: Admitted.

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

ANSWER: Defendant admits that there is an actual case or controversy between Jazz and Avadel but deny that Jazz’s allegations are valid or sustainable. Defendant denies the remaining allegations in Paragraph 54.

55. 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. For example, on information and belief, Avadel received permission from FDA to import into the United States commercially manufactured batches of its Proposed Product and has imported the product.

ANSWER: Defendant admits 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. Defendant admits that it has received permission from FDA to import into the United States batches of FT218 for commercial sale and has engaged in such importation. Defendant admits that the ’956 patent has not yet expired. Defendant denies the remaining allegations in Paragraph 55.

56. Avadel has infringed and 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.

57. Avadel has induced infringement and 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, Avadel has encouraged and 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.

58. Avadel has contributorily infringed and 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.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

62. 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 '931 Patent

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

ANSWER: Defendant incorporates its responses to the allegations in Paragraphs 1-62 as if fully set forth in this paragraph.

64. Avadel, by the submission of its NDA to the FDA, sought approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel's Proposed Product, prior to the expiration of the '931 patent.

ANSWER: Defendant admits 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. Defendant admits that the '931 patent has not yet expired. Defendant denies the remaining allegations in Paragraph 64.

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

ANSWER: Defendant admits 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. Defendant denies the remaining allegations in Paragraph 65.

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

ANSWER: Admitted.

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

ANSWER: Defendant admits that there is an actual case or controversy between Jazz and Avadel but deny that Jazz's allegations are valid or sustainable. Defendant denies the remaining allegations in Paragraph 67.

68. 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. For example, on information and belief, Avadel received permission from FDA to import into the United States commercially manufactured batches of its Proposed Product and has imported the product.

ANSWER: Defendant admits 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. Defendant admits that it has received permission from FDA to import into the United States batches of FT218 for commercial sale and has engaged in such

importation. Defendant admits that the '931 patent has not yet expired. Defendant denies the remaining allegations in Paragraph 68.

69. Avadel has infringed and 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.

70. Avadel has induced infringement and 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, Avadel has encouraged and 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.

71. Avadel has contributorily infringed and 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.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

75. 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

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

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

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

(D) 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;

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

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

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

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

(I) Costs and expenses in this action; and

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

ANSWER: Paragraphs (A)-(J) set forth Jazz's prayer for relief to which no response is required. To the extent that responses to these paragraphs are required, Defendant denies any allegations set forth therein and deny that Jazz is entitled to any relief.

DEFENSES

Subject to the responses above, upon information and belief, Defendant alleges and asserts 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, Defendant specifically reserves 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. Defendant has not infringed, does not directly infringe, and 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.

2. Defendant has not infringed, does not directly infringe, and 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.

3. Defendant has not infringed, does not directly infringe, and 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.

4. Defendant has not infringed, does not directly infringe, and 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)

5. 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.

6. 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.

7. 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.

8. 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)

9. 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)

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

FIFTH DEFENSE
(Patent Misuse)

11. By its conduct, Jazz has engaged in patent misuse by asserting infringement claims it knows or should have known are meritless.

SIXTH DEFENSE
(Equitable Defenses)

12. By its conduct, Jazz has engaged in patent misuse by asserting infringement claims it knows or should have known are meritless.

SEVENTH DEFENSE
(No Willfulness)

13. Jazz is barred from seeking and/or obtaining a finding of willfulness or receiving enhanced damages because Jazz has failed to allege Defendant engaged in any willful infringement

or reprehensible conduct and Defendant has engaged in no such conduct, which is a prerequisite for a finding of willfulness and an award of enhanced damages.

EIGHTH DEFENSE
(Attorneys' Fees)

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

NINTH DEFENSE
(Limitations on Costs)

15. 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
(Other Defenses)

16. Defendant reserves the right to supplement or amend this Answer and reserves 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*.

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 Amended 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 '488 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 '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 FT218 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).

19. 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 FT218 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 FT218 in the United States does not infringe and/or will not infringe any valid claim of the '488 patent.

20. 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 II: Declaratory Judgment of Invalidity of the '488 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 '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 FT218 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).

23. 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.

24. 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.

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

Count III: Declaratory Judgment of Non-Infringement of the ’885 Patent

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

27. 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 FT218 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).

28. 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 FT218 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 FT218 in the United States does not infringe and/or will not infringe any valid claim of the ’885 patent.

29. 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 IV: Declaratory Judgment of Invalidity of the '885 Patent

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

31. 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 FT218 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).

32. 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.

33. 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.

34. Avadel hereby seeks a declaration that the claims of the '885 patent are invalid.

Count V: Declaratory Judgment of Non-Infringement of the '956 Patent

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

36. 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 FT218 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).

37. 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 FT218 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 FT218 in the United States does not infringe and/or will not infringe any valid claim of the '956 patent.

38. 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 VI: Declaratory Judgment of Invalidity of the '956 Patent

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

40. 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 FT218 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).

41. 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.

42. 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.

43. Avadel hereby seeks a declaration that the claims of the '956 patent are invalid.

Count VII: Declaratory Judgment of Non-Infringement of the '931 Patent

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

45. 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 FT218 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).

46. 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 FT218 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 FT218 in the United States does not infringe and/or will not infringe any valid claim of the '931 patent.

47. 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 VIII: Declaratory Judgment of Invalidity of the '931 Patent

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

49. 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 FT218 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).

50. 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.

51. 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.

52. 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 Amended 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.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Defendant Avadel CNS Pharmaceuticals, LLC demands a jury trial on all issues so triable.

Dated: July 10, 2023

MCCARTER & ENGLISH, LLP

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