IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

JAZZ PHARMACEUTICALS, INC.'S ANSWER TO
AVADEL CNS PHARMACEUTICALS LLC'S COUNTERCLAIMS

Jazz Pharmaceuticals, Inc. ("Jazz Pharmaceuticals"), by its undersigned attorneys, hereby answers the Counterclaims to its Complaint for Patent Infringement by Defendant Avadel CNS Pharmaceuticals LLC ("Avadel"), dated June 3, 2021 (the "Counterclaims"), as follows. Except as expressly admitted, all allegations are denied.

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.

ANSWER: Paragraph 1 states legal conclusions for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that this Court has subject matter jurisdiction over Avadel's counterclaims as to US. 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"), denies that Avadel is

entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 1.

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

ANSWER: Paragraph 2 states legal conclusions for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that this Court has subject matter jurisdiction over Avadel's counterclaims as to the patents-in-suit, denies that Avadel is entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 2.

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

ANSWER: Paragraph 3 states legal conclusions for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that venue is proper to adjudicate this action and, except as so admitted, denies the allegations of paragraph 3.

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.

ANSWER: Jazz Pharmaceuticals admits on information and belief the allegations of paragraph 4.

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.

ANSWER: Jazz Pharmaceuticals admits the allegations of paragraph 5.

AVADEL'S 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.

ANSWER: Jazz Pharmaceuticals admits that U.S. Patent No. 10,272,062 (the "'062 patent") is titled, "Modified release gamma-hydroxybutyrate formulations having improved pharmacokinetics," lists July 21, 2017 as the filing date, and lists April 30, 2019 as the issue date. Jazz Pharmaceuticals further admits on information and belief that the '062 patent covers Avadel's proposed sodium oxybate product, code named FT218. Jazz Pharmaceuticals lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 6 and, therefore, denies those allegations.

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.

ANSWER: Jazz Pharmaceuticals admits that the '062 patent lists January 25, 2018 as the publication date of the underlying patent application, and, except as so admitted, denies the allegations of paragraph 7.

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.

ANSWER: Jazz Pharmaceuticals admits on information and belief that Avadel's published data concerning the pharmacokinetic properties of Avadel's proposed sodium oxybate product, FT218, correspond to the Examples of Avadel's '062 patent, that at least Example 1 and Example 1bis of Avadel's '062 patent are covered by Jazz Pharmaceuticals' '488, '885, '956, and '931 patents, and, except as so admitted, denies the allegations of paragraph 8.

9. The '062 application disclosed modified release formulations of gammahydroxybutyrate ("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.

ANSWER: Jazz Pharmaceuticals admits that the ’062 patent discloses formulations of sodium oxybate containing methacrylic acid-methyl methacrylate co-polymers, that the ’062 patent further discloses dissolution properties of sodium oxybate formulations, refers to the text and claims of the ’062 patent for the contents thereof, and otherwise denies the allegations of paragraph 9.

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.

ANSWER: Jazz Pharmaceuticals admits that it filed U.S. Patent Application No. 13/071,369 (the “’369 application”) on March 24, 2011, refers to the text, claims, and file history of the ’369 application for the contents thereof, and otherwise denies the allegations of paragraph 10.

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.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file history of the '369 application for the contents thereof, and otherwise denies the allegations of paragraph 11.

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).

ANSWER: Jazz Pharmaceuticals admits that it filed U.S. Patent Application No. 16/025,487 (the "'487 application") on July 2, 2018 as a continuation of the '369 application, that the '487 application issued as the '488 patent on September 1, 2020, refers to the text, claims, and file history of the '488 patent for the contents thereof, and otherwise denies the allegations of paragraph 12.

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.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file history of the '488 patent for the contents thereof, and otherwise denies the allegations of paragraph 13.

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 acidmethyl 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.

ANSWER: Jazz Pharmaceuticals admits that it filed U.S. Patent Application No. 16/916,677 (the “’677 application”) on June 30, 2020 as a continuation of U.S. Patent Application No. 16/712,260, which was a continuation of the ’487 application, that the ’677 application issued as the ’885 patent on October 27, 2020, refers to the text, claims, and file history of the ’885 patent for the contents thereof, and otherwise denies the allegations of paragraph 14.

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.

ANSWER: Jazz Pharmaceuticals admits that it filed U.S. Patent Application No. 17/012,823 (the “’823 application”) on September 4, 2020 as a continuation of the ’677 application, that the ’823 application issued as the ’956 patent on March 30, 2021, refers to the text, claims, and file history of the ’956 patent for the contents thereof, and otherwise denies the allegations of paragraph 15.

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.

ANSWER: Jazz Pharmaceuticals admits that it filed U.S. Patent Application No. 17/012,831 (the "'831 application") on September 4, 2020 as a continuation of the '677 application, that the '831 application issued as the '931 patent on April 6, 2021, refers to the text, claims, and file history of the '931 patent for the contents thereof, and otherwise denies the allegations of paragraph 16.

Count I: Declaratory Judgment of Alleged 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.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

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).

ANSWER: Paragraph 18 states a legal conclusion for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that a justiciable controversy exists between Avadel and Jazz Pharmaceuticals regarding the '963 patent, that Jazz Pharmaceuticals owns the '963 patent, that Avadel's filing of a New Drug Application ("NDA") to commercially market Avadel's proposed sodium oxybate drug product before the '963 patent expires infringes at least claim 1 of the '963 patent under 35 U.S.C. § 271(e), that the making, using, offering to sell, selling, and/or importation of Avadel's proposed sodium oxybate drug product will infringe at least claim 1 of the '963 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), and, except as so admitted, denies the allegations of paragraph 18.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 19.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 20.

Count II: Declaratory Judgment of Alleged 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.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

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).

ANSWER: Paragraph 22 states a legal conclusion for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that a justiciable controversy exists between Avadel and Jazz Pharmaceuticals regarding the '963 patent, that Avadel's filing of an NDA to commercially market Avadel's proposed sodium oxybate drug product before the '963 patent expires infringes at least claim 1 of the '963 patent under 35 U.S.C. § 271(e), that the making, using, offering to sell, selling, and/or importation of Avadel's proposed sodium oxybate drug product will infringe at least claim 1 of the '963 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), and, except as so admitted, denies the allegations of paragraph 22.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 23.

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

ANSWER: Jazz Pharmaceuticals admits that Avadel purports to seek a declaration that the claims of the '963 patent are invalid, denies that Avadel is entitled to the relief that it seeks and, except as so admitted, denies the allegations of paragraph 24.

Count III: Declaratory Judgment Alleging Required Delisting of the '963 Patent

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

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

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

ANSWER: Jazz Pharmaceuticals admits that Avadel purports to seek an order requiring Jazz Pharmaceuticals to remove the '963 patent from the United States Food and Drug Administration ("FDA") publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") listing with respect to XYREM®, denies that Avadel is entitled to the relief that it seeks, and denies all other allegations of paragraph 26.

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.

ANSWER: Jazz Pharmaceuticals admits that 21 C.F.R. § 314.53(c) contains regulations relating to the submission of patent information to the FDA, refers to the regulations for the terms thereof and, except as so admitted, denies the allegations of paragraph 27.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 28.

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."

ANSWER: Jazz Pharmaceuticals admits that it submitted the use code U-1110, method of treating a patient with a prescription drug using a computer database in a computer system for distribution, to the FDA with respect to the Orange Book listing for the '963 patent for XYREM®, and, except as so admitted, denies the allegations of paragraph 29.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 30.

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.

ANSWER: Jazz Pharmaceuticals admits that Avadel purports to seek a declaration ordering Jazz Pharmaceuticals to remove the '963 patent from the Orange Book, denies that Avadel is entitled the relief that it seeks and, except as so admitted, denies the allegations of paragraph 31.

Count IV: Declaratory Judgment of Alleged 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.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

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).

ANSWER: Paragraph 33 states a legal conclusion for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that a justiciable controversy exists between Avadel and Jazz Pharmaceuticals regarding the '488 patent, that Jazz Pharmaceuticals owns the '488 patent, that Avadel's filing of an NDA to commercially market Avadel's proposed sodium oxybate drug product before the '488 patent expires infringes at least claim 1 of the '488 patent under 35 U.S.C. § 271(e), that the making, using, offering to sell, selling, and/or importation of Avadel's proposed sodium oxybate drug product will infringe at least claim 1 of the '488 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), and, except as so admitted, denies the allegations of paragraph 33.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 34.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 35.

Count V: Declaratory Judgment of Alleged 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.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

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).

ANSWER: Paragraph 37 states a legal conclusion for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that a justiciable controversy exists between Avadel and Jazz Pharmaceuticals regarding the '488 patent, that Avadel's filing of an NDA to commercially market Avadel's proposed sodium oxybate drug product before the '488 patent expires infringes at least claim 1 of the '488 patent under 35 U.S.C. § 271(e), that the making, using, offering to sell, selling, and/or importation of Avadel's proposed sodium oxybate drug product will infringe at least claim 1 of the '488 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), and, except as so admitted, denies the allegations of paragraph 37.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 38.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 39.

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

ANSWER: Jazz Pharmaceuticals admits that Avadel purports to seek a declaration that the claims of the '488 patent are invalid, denies that Avadel is entitled to the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 40.

Count VI: Declaratory Judgment of Alleged 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.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

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).

ANSWER: Paragraph 42 states a legal conclusion for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that a justiciable controversy exists between Avadel and Jazz Pharmaceuticals regarding the '885 patent, that Jazz Pharmaceuticals owns the '885 patent, that Avadel's filing of an NDA to commercially market Avadel's proposed sodium oxybate drug product before the '885 patent expires infringes at least claim 1 of the '885 patent under 35 U.S.C. § 271(e), that the making, using, offering to sell, selling, and/or importation of Avadel's proposed sodium oxybate drug product will infringe at least claim 1 of the '885 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), and, except as so admitted, denies the allegations of paragraph 42.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 43.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 44.

Count VII: Declaratory Judgment of Alleged 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.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

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).

ANSWER: Paragraph 46 states a legal conclusion for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that a justiciable controversy exists between Avadel and Jazz Pharmaceuticals regarding the '885 patent, that Avadel's filing of an NDA to commercially market Avadel's proposed sodium oxybate drug product before the '885 patent expires infringes at least claim 1 of the '885 patent under 35 U.S.C. § 271(e), that the making, using, offering to sell, selling, and/or importation of Avadel's proposed sodium oxybate drug product will infringe at least claim 1 of the '885 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), and, except as so admitted, denies the allegations of paragraph 46.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 47.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 48.

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

ANSWER: Jazz Pharmaceuticals admits that Avadel purports to seek a declaration that the claims of the '885 patent are invalid, denies that Avadel is entitled to the relief that it seeks and, except as so admitted, denies the allegations of paragraph 49.

Count VIII: Declaratory Judgment of Alleged 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.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

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).

ANSWER: Paragraph 51 states a legal conclusion for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that a justiciable controversy exists between Avadel and Jazz Pharmaceuticals regarding the '956 patent, that Jazz Pharmaceuticals owns the '956 patent, that Avadel's filing of an NDA to commercially market

Avadel's proposed sodium oxybate drug product before the '956 patent expires infringes at least claim 1 of the '956 patent under 35 U.S.C. § 271(e), that the making, using, offering to sell, selling, and/or importation of Avadel's proposed sodium oxybate drug product will infringe at least claim 1 of the '956 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), and, except as so admitted, denies the allegations of paragraph 51.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 52.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 53.

Count IX: Declaratory Judgment of Alleged 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.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

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).

ANSWER: Paragraph 55 states a legal conclusion for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that a justiciable controversy

exists between Avadel and Jazz Pharmaceuticals regarding the '956 patent, that Avadel's filing of an NDA to commercially market Avadel's proposed sodium oxybate drug product before the '956 patent expires infringes at least claim 1 of the '956 patent under 35 U.S.C. § 271(e), that the making, using, offering to sell, selling, and/or importation of Avadel's proposed sodium oxybate drug product will infringe at least claim 1 of the '956 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), and, except as so admitted, denies the allegations of paragraph 55.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 56.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 57.

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

ANSWER: Jazz Pharmaceuticals admits that Avadel purports to seek a declaration that the claims of the '956 patent are invalid, denies that Avadel is entitled to the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 58.

Count X: Declaratory Judgment of Alleged 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.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

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).

ANSWER: Paragraph 60 states a legal conclusion for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that a justiciable controversy exists between Avadel and Jazz Pharmaceuticals regarding the '931 patent, that Jazz Pharmaceuticals owns the '931 patent, that Avadel's filing of an NDA to commercially market Avadel's proposed sodium oxybate drug product before the '931 patent expires infringes at least claim 1 of the '931 patent under 35 U.S.C. § 271(e), that the making, using, offering to sell, selling, and/or importation of Avadel's proposed sodium oxybate drug product will infringe at least claim 1 of the '931 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), and, except as so admitted, denies the allegations of paragraph 60.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 61.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 62.

Count XI: Declaratory Judgment of Alleged 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.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

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).

ANSWER: Paragraph 64 states a legal conclusion for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that a justiciable controversy exists between Avadel and Jazz Pharmaceuticals regarding the '931 patent, that Avadel's filing of an NDA to commercially market Avadel's proposed sodium oxybate drug product before the '931 patent expires infringes at least claim 1 of the '931 patent under 35 U.S.C. § 271(e), that the making, using, offering to sell, selling, and/or importation of Avadel's proposed sodium oxybate drug product will infringe at least claim 1 of the '931 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), and, except as so admitted, denies the allegations of paragraph 64.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 65.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 66.

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

ANSWER: Jazz Pharmaceuticals admits that Avadel purports to seek a declaration that the claims of the '931 patent are invalid, denies that Avadel is entitled to the relief that it seeks and, except as so admitted, denies the allegations of paragraph 67.

AVADEL'S PRAYER FOR RELIEF

Jazz Pharmaceuticals denies that Avadel is entitled to any relief on its Counterclaims, either as prayed for in its pleading or otherwise.

JAZZ PHARMACEUTICALS' AFFIRMATIVE DEFENSE

Without prejudice to the denials set forth in this Answer and to the ability to amend this Answer to seek and allege any and all defenses not presently known or that are revealed during the course of discovery or otherwise, Jazz Pharmaceuticals asserts the following affirmative defense in response to Avadel's Counterclaims:

Failure to State a Claim

The Counterclaims fail to state any claim for which relief may be granted.

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June 18, 2021

CERTIFICATE OF SERVICE

I hereby certify that on June 18, 2021, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 18, 2021, upon the following in the manner indicated:

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