IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-691 (GBW)
	)	
AVADEL CNS PHARMACEUTICALS LLC,	)	
	)	
Defendants.	)	
	)	

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

Jazz Pharmaceuticals, Inc. ("Jazz Pharmaceuticals"), by its undersigned attorneys, hereby submits its Second Amended Answer to the Counterclaims to its Complaint for Patent Infringement by Defendant Avadel CNS Pharmaceuticals LLC ("Avadel"), dated July 10, 2022 (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.*

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 sodium oxybate product, code named FT218, and commercially marketed as LUMRYZ™. 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 Amended 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 sodium oxybate product, FT218, commercially marketed as LUMRYZ™, 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 '488 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 '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).

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 '488 patent, that Jazz Pharmaceuticals owns the '488 patent, that the making, using, offering to sell, selling, and/or importation of Avadel's sodium oxybate drug product infringes 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 18.

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.

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 '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 20.

Count II: Declaratory Judgment of Alleged 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.

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

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).

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 '488 patent, that the making, using, offering to sell, selling, and/or importation of Avadel's sodium oxybate drug product infringes 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 22.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 23.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 24.

25. 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 25.

Count III: Declaratory Judgment of Alleged 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.

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

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).

ANSWER: Paragraph 27 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 the making, using, offering to sell, selling, and/or importation of Avadel's sodium oxybate drug product infringes 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 27.

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 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 28.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 29.

Count IV: Declaratory Judgment of Alleged 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.

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

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).

ANSWER: Paragraph 31 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 the making, using, offering to sell, selling, and/or importation of Avadel's sodium oxybate drug product

infringes 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 31.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 32.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 33.

34. 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 34.

Count V: Declaratory Judgment of Alleged 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.

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

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).

ANSWER: Paragraph 36 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 the making, using, offering to sell, selling, and/or importation of Avadel’s sodium oxybate drug product infringes 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 36.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 37.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 38.

Count VI: Declaratory Judgment of Alleged 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.

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

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).

ANSWER: Paragraph 40 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 the making, using, offering to sell, selling, and/or importation of Avadel's sodium oxybate drug product infringes 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 40.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 41.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 42.

43. 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 43.

Count VII: Declaratory Judgment of Alleged 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.

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

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).

ANSWER: Paragraph 45 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 the making, using, offering to sell, selling, and/or importation of Avadel's sodium oxybate drug product infringes 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 45.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 46.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 47.

Count VIII: Declaratory Judgment of Alleged 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.

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

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).

ANSWER: Paragraph 49 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 the making, using, offering to sell, selling, and/or importation of Avadel's sodium oxybate drug product infringes 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 49.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 50.

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.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 51.

52. 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 52.

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.

AVADEL'S DEMAND FOR JURY TRIAL

Jazz Pharmaceuticals admits that it is appropriate for there to be a jury trial on all issues so triable.

JAZZ PHARMACEUTICALS' AFFIRMATIVE DEFENSES

1. 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 defenses in response to Avadel's Counterclaims:

I. Failure to State a Claim

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

II. Judicial Estoppel and Unclean Hands

3. In Civil Action Nos. Nos. 21-691, 21-1138, and 21-1594, Avadel's counterclaims seeking declaratory judgments of invalidity against Patent Nos. 10,758,488 ("the '488 Patent"), 10,813,885 ("the '885 Patent"), 10,959,956 ("the '956 Patent"), 10,966,931 ("the '931 Patent"), 11,077,079 ("the '079 Patent"), and 11,147,782 ("the '782 Patent") are barred, in whole or in part, under the equitable principles of estoppel and/or unclean hands.

A. Avadel's Inconsistent Positions Regarding the Jazz Sustained Release Patents

4. In this litigation, Avadel collectively refers to the '488 Patent, the '885 Patent, the '956 Patent, and the '931 Patent as the "Jazz Sustained Release Patents."

5. Avadel owns U.S. Patent No. 10,272,062 ("the '062 Patent"), which it prosecuted from July 2017 to April 2019. *See* Case No. 21-691, D.I. 11 at Counterclaim ¶ 6. Avadel refers to the patent application that led to the issuance of '062 Patent as the "'062 Application". *See id.* at ¶ 7.

6. Avadel has taken the position in this litigation that Jazz drafted the claims of each of the Jazz Sustained Release Patents "***solely based*** on Avadel Ireland's inventive work disclosed in at least the '062 Application." *See id.* at ¶ 13 (emphasis added); *see also id.* at ¶¶ 14-16.[1]

7. Avadel has also asserted in this litigation that fourteen alleged prior art references "anticipate and/or render obvious, either alone or in combination, the asserted claims of the . . . Jazz Sustained Release Patents." Ex. A, Avadel 10-13-21 Contentions at 4-5.

8. One of the references that Avadel contends "anticipate[s] and/or render[s] obvious" the asserted claims of the Jazz Sustained Release Patents is U.S. Patent No. 5,594,030, which issued to Ubaldo Conte et al. in 1997 (hereafter, "Conte 1997").

9. During prosecution of the '062 Patent—which Avadel contends is the sole basis for the claims of the Jazz Sustained Release Patents—Avadel argued to the United States Patent and Trademark Office ("USPTO") that Conte 1997 ***would not*** have taught or suggested the use of methacrylic acid-methyl methacrylate co-polymers in a sustained release GHB formulation, as is claimed in each asserted claim of the Jazz Sustained Release Patents. Instead, Avadel represented to the USPTO that "the coating of Conte [1997]'s compositions comprises

[1] Jazz Pharmaceuticals denies this claim.

copolymers that do not carry free carboxylic groups," and that "Conte [1997] provides no suggestion or rationale that would lead a person of ordinary skill in the art to modify the film coatings disclosed therein and include a polymer having free carboxylic groups," such as the claimed methacrylic acid-methyl methacrylate co-polymers. *See, e.g.*, Ex. B, App. No. 15/655,924, September 4, 2018 Response to Office Action at 12.

10. During prosecution of the '062 Patent, Avadel further represented to the USPTO that instead of rendering obvious a once-nightly GHB formulation, Conte 1997 would have affirmatively taught away from such an invention. Avadel represented to the USPTO that "Conte [1997] does ***not*** disclose or suggest a gamma-hydroxybutyrate composition in a unit dose suitable for administration only once-nightly," and that "[b]y requiring multiple doses (2 or more) during the day, and at substantially lower dosages to alleviate addiction symptoms in an awake state, Conte [1997] clearly teaches away." *Id.* at 12-13 (emphasis in original).

11. Avadel also relies on U.S. Patent Publication No. 2006/0210630 to Liang et al. (hereafter, "Liang 2006") in support of its assertion in this litigation that the Jazz Sustained Release Patents are invalid. More specifically, Avadel has taken the position in this litigation that the asserted claims of the Jazz Sustained Release Patents are obvious over Liang 2006, purportedly because the reference "discloses [GHB] formulations made up of an immediate release portion and a delayed/controlled release portion," and "[a]s in the Jazz Sustained Release Patent claims, Liang 2006's delayed/controlled release formulations are made up of a functional coating deposited over a core, with the core comprising gamma-hydroxybutyric acid salts and the functional coating comprising a pH sensitive enteric release coat such as a methacrylic acid-methyl methacrylate co-polymer." Ex. A, Avadel 10-13-21 Contentions at 20.

12. But Avadel advanced the exact opposite position during prosecution of the '062 Patent, arguing that Liang 2006 would ***not*** have rendered obvious a sustained release GHB formulation comprised of a functional coating containing 20-50 percent by weight methacrylic acid-methyl methacrylate co-polymers, as claimed in the Jazz Sustained Release Patents. Specifically, Avadel has represented to the USPTO that "Liang [2006] teaches that the compositions disclosed therein provide 'a convenient once nightly or once daily dose regiment for the oral delivery of one or more gamma-hydroxybutyric salts.' Thus, Liang [2006] provides no teaching or suggestion that would prompt a person of ordinary skill in the art to modify the coating of the delayed/controlled release component disclosed therein." *See* Ex. B, App. No. 15/655,924, September 4, 2018 Response to Office Action at 15.

13. Avadel's position in this litigation and its position before the USPTO are diametrically opposed. Avadel has taken the position in this litigation that Liang 2006—standing alone—renders the formulations claimed in the Jazz Sustained Release Patents obvious, but Avadel has taken the position before the USPTO that Liang 2006 would provide zero motivation to modify its disclosures to cover a formulation with the characteristics claimed in the Jazz Sustained Release Patents.

14. Avadel further advocated before the USPTO during prosecution of the '062 Patent that the data presented in Liang 2006 would not have given rise to any reasonable expectation that formulations that differ from those expressly disclosed in Laing 2006 would work for their intended purpose or exhibit any desired pharmacokinetic profile. Specifically, Avadel advocated that pharmacokinetic targets "could not be predicted" based upon the disclosures of Liang 2006. Ex. B, App. No. 15/655,924, September 4, 2018 Response to Office Action at 18.

15. Avadel also prosecuted U.S. Patent Nos. 10,736,866 ("the '866 Patent"), 10,952,986 ("the '986 Patent") and 10,973,795 ("the '795 Patent") prior to the initiation of this litigation. The '866 Patent is a continuation of the '062 Patent, and both the '986 and '795 Patents are continuations of the '866 Patent. All of these patents therefore contain substantively similar (if not identical) disclosures in their specifications.

16. Avadel continued to remark upon the Liang 2006 reference during prosecution of the '866 Patent, the '986 Patent, and the '795 Patent. Specifically, during prosecution of the '795 Patent, Avadel argued that, rather than give rise to any reasonable expectation regarding the properties of GHB formulations that differ from those expressly disclosed in Laing 2006, "**[u]sing Liang [2006] to guess the in vivo pharmacokinetic profile of [another] claimed invention would be pure speculation**." *See* Ex. C, Application No. 16/419,616, September 17, 2020 Response to Office Action at 10 (emphasis in original). During prosecution of the '866 Patent, Avadel represented to the USPTO that "because the dosage forms of Liang [2006] differ from the claimed formulation[s], a person of ordinary skill in the art would expect that pharmacokinetic properties would also differ." *See* Ex. D, Application No. 16/281,235, March 18, 2020 Response to Office Action at 21; *see also id.* at 19 (Avadel further arguing to the USPTO that "a person of ordinary skill in the art would not be prompted by the disclosure of Liang [2006] to modify the dosage forms disclosed therein"). And during prosecution of the '986 Patent, Avadel took the position that "[t]he unpredictability of GHB formulations is not merely academic . . . there is no reasonable predictability with respect to GHB formulations, even if a skilled artisan were trying to copy a formulation exactly. It's simply too unpredictable." Ex. E, App. No. 16/420,321, October 1, 2020 Response to Office Action at 9.

17. In sum, according to Avadel's own sworn statements to the USPTO, a POSA would not have been: (1) motivated to modify the disclosures of Liang 2006 or (2) able to reasonably expect that ***any*** sustained release formulation of GHB (let alone the claimed formulations of the Jazz Sustained Release Patents, with a functional coating comprised of 20-50 percent by weight methyl methacrylate, methacrylic acid copolymers) would demonstrate the claimed pharmacokinetic profiles based upon the disclosures of Liang 2006. Avadel has taken the opposite position in this litigation. *See* Ex. A, Avadel 10-13-21 Contentions at 20-25.

18. As set forth above, Avadel represented to the USPTO that Conte 1997 and Liang 2006 would not have rendered its GHB formulations obvious during prosecution of Avadel's Patent Application Nos. 15/655,924, 16/281,235, 16/419,616, and/or 16/420,321. Each of these Patent Applications issued as U.S. Patents (the '062 Patent, the '866 Patent, the '986 Patent, and the '795 Patent, respectively). Therefore, Avadel derived a benefit from the arguments it made to the USPTO in support of its patent applications.

B. Avadel's Inconsistent Positions Regarding the Jazz Resinate Patents

19. In this litigation, Avadel refers to the '079 Patent and the '782 Patent collectively as "the Jazz Resinate Patents."

(i). Avadel's Inconsistent Positions Regarding the '079 Patent

20. Avadel has taken the position in this litigation that the asserted claims of the '079 Patent "are generally directed to a method of treating narcolepsy with a single-dose oxybate formulation comprising opening a sachet containing a solid oxybate formulation comprising a mixture of immediate release and controlled release components and mixing the formulation with water for oral administration to a patient." Ex. F, Avadel 1-14-22 Contentions at 9-10.

21. Avadel has taken the position in this litigation that Liang 2006 anticipates the asserted claims of the '079 Patent. *See id.* at 10-11.

22. Avadel has also asserted in this litigation that eighteen alleged prior art references "anticipate and/or render obvious, either alone or in combination, the asserted claims of the '079 patent." *Id.* at 4-6.

23. As set forth below, these arguments are directly contradictory to arguments that Avadel has made before the USPTO.

24. Avadel asserts in the instant litigation that "Jazz, through its prosecution counsel, copied the claimed invention" of the '079 Patent from Avadel's then-pending Application No. 16/420,321 ("the '321 Application"). *See id.* at 65-69.[2] The '321 Application subsequently issued as the '986 Patent.

25. Avadel further asserts that the pending method claim that Jazz allegedly "copied" from the '321 Application into the '079 Patent was comprised of the following elements:

> A method of treating a disorder treatable with gamma-hydroxybutyrate in a human in need thereof, the method comprising:
>
> > administering a single daily dose to said human, the single daily dose comprising an amount of gamma-hydroxybutyrate equivalent to from 3.0 to 12.0 g of sodium oxybate, wherein the administering comprises
> >
> > > opening a sachet containing a gamma-hydroxybutyrate formulation,
> > >
> > > mixing the formulation with water, and
> > >
> > > orally administering the mixture.

See id. at 68; *see also* Ex. E, App. No. 16/420,321, October 1, 2020 Response to Office Action at 2.

[2] Jazz Pharmaceuticals denies this claim.

26. In 2020, the USPTO rejected this pending claim of the '321 Application as unpatentable over Liang 2006 in view of U.S. Patent App. Pub. No. 2002/0077334 to Cook et al. ("Cook 2002"). In response to that rejection, Avadel represented to the USPTO that Liang 2006 does "not expressly disclose opening a sachet containing a gamma hydroxybutyrate formulation, mixing the formulation with water and orally administering the mixture." *See* Ex. E, App. No. 16/420,321, October 1, 2020 Response to Office Action at 8.

27. Avadel has taken the opposite position in this litigation, arguing that Liang 2006 "discloses that the solid dosage form could be a sachet," and that "Liang 2006 discloses that the formulation could be stirred into a drink, and water is the most common form of drink." Ex. F, Avadel 1-14-22 Contentions at 10-11.

28. Avadel has also taken the position in this litigation that, to the extent that Liang 2006 is not found to anticipate claim 1 of the '079 Patent, that claim would "have been obvious to a POSA as of the earliest asserted priority date of the '079 patent [i.e., February 2015]," purportedly because "a POSA would have been motivated to develop a method for treating narcolepsy by administering a single daily dosage of GHB containing an immediate release component and a controlled release component in a sachet form." Ex. F, Avadel 1-14-22 Contentions at 11-12.

29. Avadel took the opposite position before the USPTO in October 2020 during prosecution of the '321 Application. More specifically, Avadel stated to the Patent Office that, at the time of alleged invention for the methods claimed in the '321 Application (2016), the prior art "***teaches away*** from a sachet as currently claimed." Ex. E, App. No. 16/420,321, October 1, 2020 Response to Office Action at 8 (emphasis in original). Avadel represented to the USPTO that the prior art disclosed "inherent problems" with sachet formulations and thus would have

taught a POSA to abandon the "problematic" sachet formulation "in favor of a purely liquid formulation." *Id.* Avadel further stated that there would be no reasonable expectation of success of formulating GHB into a sachet because "there are known problems of instability, microbial growth, and/or degradation of the GHB active ingredient into GBL," which Avadel stated would have taught away from a sachet formulation. *Id.* at 8-9. Thus, contrary to Avadel's position in this litigation that a POSA "***would have been motivated*** to develop a method for treating narcolepsy by administering a single daily dosage of GHB containing an immediate release component and a controlled release component in a sachet form" in 2015, Avadel expressly argued to the USPTO that, in 2016, "given the ***teachings away***" in the prior art, the prior art would "fail to provide an apparent reason that would have prompted a person of ordinary skill in the art in the relevant field to combine the elements in the way the claimed invention does with a reasonable expectation of success, as required by the law." *Id.* at 9.

30. The '321 Application issued as a U.S. Patent after Avadel overcame the obviousness rejection based upon Liang 2006 and Cook 2002. Therefore, Avadel derived a benefit from the arguments that it made to the USPTO.

(ii). Avadel's Inconsistent Positions Regarding the '782 Patent

31. Avadel has taken the position in this litigation that the asserted claims of the '782 Patent are "generally directed to a formulation or a unit dose of GHB with specific viscosity enhancing agents, acid, lubricants, amounts of GHB, or blood concentrations of GHB following administration of the claimed formulation." Ex. F, Avadel 1-14-22 Contentions at 27.

32. In this litigation, Avadel also contends that the claims of the '782 Patent were written after Jazz Pharmaceuticals allegedly "copied the claims from Avadel's application that led to the issuance of the '866 patent." *Id.* at 71.[3]

33. Avadel further argues in the present litigation that the asserted claims of the '782 Patent are obvious in view of Liang 2006. Specifically, Avadel asserts in this case that "Liang 2006 discloses all of the limitations of claim 1 other than a viscosity enhancing agent and acid that are separate from the immediate release and modified release particles." *Id.* at 28. Avadel further argues that "the addition of an acid and/or a viscosity enhancing agent separate from the immediate and modified release particles was well-known in the art as part of a multi-particulate drug form," and that "a POSA would have been motivated to modify the formulations in Liang 2006 . . . to include an acid and/or viscosity enhancing agent separate from the immediate and modified release particles of GHB with a reasonable expectation of arriving at the claimed formulation." *Id.* at 30.

34. As set forth below, this argument stands in direct contradiction to representations that Avadel made to the USPTO in March 2020, during the prosecution of Avadel's Patent Application No. 16/281,235 ("the '235 Application"), which led to the '866 Patent. In March 2020, then-pending claim 1 of the '235 Application was as follows:

A formulation of gamma-hydroxybutyrate comprising:

an immediate release portion comprising gamma-hydroxybutyrate;

a modified release portion comprising gamma-hydroxybutyrate;

a suspending or viscosifying agent . . .

an acidifying agent . . .

[3] Jazz Pharmaceuticals denies this claim.

> wherein the suspending or viscosifying agent and the acidifying agent are separate and distinct from the immediate release portion and the modified release portion; and
>
> wherein the ratio of gamma-hydroxybutyrate in the immediate release portion and the modified release portion is from 10/90 to 65/35.

See Ex. D, App. No. 16/281,235, March 18, 2020 Response to Office Action at 2.

35. Avadel contends in the instant litigation that Jazz "copied" this claim into the '782 Patent. Ex. F, Avadel 1-14-22 Contentions at 70-71.

36. The USPTO rejected claim 1 of the '235 Application as unpatentable over Liang 2006. In response to that rejection, Avadel stated to the USPTO that Liang 2006 would not render obvious the claimed formulation, because "Liang [2006]'s only teaching regarding excipients is that they have to be actually part of Liang [2006]'s immediate release and delayed/controlled release components. As such, nowhere does Liang [2006] disclose or suggest a formulation having a suspending / viscosifying agent and an acidifying agent that are separate and distinct from the immediate release component and the delayed/controlled release component of the formulation." Ex. D, App. No. 16/281,235, March 18, 2020 Response to Office Action at 18. Avadel further represented to the USPTO that "a person of ordinary skill in the art would not be prompted by the disclosure of Liang [2006] to modify the dosage forms discussed therein and arrive at the claimed formulation with a reasonable expectation of success." *Id.* at 19. This directly contradicts the obviousness arguments Avadel has made in this litigation with respect to the '782 Patent.

37. The '235 Application issued as a U.S. Patent after Avadel overcame the obviousness rejection based upon Liang 2006. Therefore, Avadel derived a benefit from the arguments made to the USPTO and set forth above.

C. Avadel is Estopped, Under Principles of Judicial Estoppel and/or the Doctrine of Unclean Hands, from Seeking Declaratory Judgments that the Asserted Claims of the Jazz Sustained Release Patents and Jazz Resinate Patents Are Invalid As Anticipated or Obvious In View of Its Inconsistent Arguments to the USPTO

38. As set forth above, Avadel has made invalidity arguments in this litigation that are inconsistent with—and in many cases the exact opposite of—validity arguments that Avadel made under the penalty of perjury to the USPTO.

39. Based upon: (1) Avadel's derivation and validity contentions, (2) the fact that the patent applications to which the inventions claimed in the Jazz Sustained Release Patents and the Jazz Resinate Patents claim priority were filed before Avadel's alleged inventions, and (3) Avadel's positions before the USPTO, Avadel is estopped from raising any arguments pursuant to 35 U.S.C. §§ 102 or 103 against the Jazz Sustained Release Patents and the Jazz Resinate Patents in this case.

40. Avadel gained an advantage by making the aforementioned validity arguments to the USPTO, having overcome the USPTO's obviousness rejections in view of those arguments and obtaining issued U.S. patents as a result.

41. It would be unconscionable to allow Avadel to maintain positions in this litigation that are inconsistent with positions Avadel has taken before the USPTO and from which Avadel derived a clear benefit; namely, the issuance of U.S. Patents from its Patent Application Nos. 15/655,924, 16/281,235, 16/419,616, and/or 16/420,321.

42. Avadel's derived benefits from the grant of the '062, '986, '886, and '795 Patents relate to the subject matter of this litigation because Avadel argues that Jazz copied the novel inventions of the Jazz Sustained Release Patents and Jazz Resinate Patents from the Avadel '062, '986, '886, and '795 Patents, but at the same time argues that Jazz Pharmaceuticals' inventions in the Jazz Sustained Releases Patents and Jazz Resinate Patents are invalid over references that

Avadel overcame during prosecution of the Avadel '062, '986, '886, and '795 Patents by making contradictory arguments earlier in time.

43. Avadel's inconsistent positions constitute unconscionable and bad-faith actions that directly relate to this litigation, are intended to injure Jazz Pharmaceuticals (and its rights in the Jazz Sustained Release Patents and Jazz Resinate Patents), and affect the balance of equities between Avadel and Jazz Pharmaceuticals.

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July 31, 2023

CERTIFICATE OF SERVICE

I hereby certify that on July 31, 2023, 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 July 31, 2023, upon the following in the manner indicated:

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