IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Jazz Pharmaceuticals, Inc. ("Jazz Pharmaceuticals" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC (collectively "Avadel" or "Defendants"), alleges as follows:

Nature of the Action

1. This is an action for patent infringement and for a declaratory judgement of patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.* and 28 U.S.C. §§ 2201 and 2202, arising from Avadel's filing of a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a sodium oxybate drug product prior to the expiration of United States Patent Nos. 8,731,963 (the "'963 patent"), 10,758,488 (the "'488 patent"), 10,813,885 (the "'885 patent"), 10,959,956

(the "'956 patent"), and 10,966,931 (the "'931 patent") owned by Jazz Pharmaceuticals (collectively, "the patents-in-suit").

The Parties

2. Plaintiff Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3170 Porter Drive, Palo Alto, California 94304.

3. On information and belief, Defendant Avadel Pharmaceuticals plc is a corporation organized and existing under the laws of Ireland, having a principal place of business at 10 Earlsfort Terrace, Dublin 2, Ireland, D02 T380. On information and belief, Avadel Pharmaceuticals plc is in the business of, *inter alia*, developing, manufacturing, marketing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its affiliates, including Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC.

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

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

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

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

8. On information and belief, Defendant Avadel Management Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. On information and belief, Avadel Management Corporation is in the business of, *inter alia*, developing, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical

products throughout the United States, including within this District, either on its own or through its affiliates, including Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, and Avadel CNS Pharmaceuticals LLC.

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

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

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

Jurisdiction and Venue

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

13. On information and belief, Avadel Pharmaceuticals plc is subject to personal jurisdiction in Delaware because Avadel Pharmaceuticals plc has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. On information and belief, Avadel Pharmaceuticals plc manufactures, markets, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

14. On information and belief, Avadel US Holdings, Inc. is subject to personal jurisdiction in Delaware because Avadel US Holdings, Inc. has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel US Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Avadel US Holdings, Inc. manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel US Holdings, Inc. is registered to do business in Delaware (business identification number 5123065) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

15. On information and belief, Avadel Specialty Pharmaceuticals, LLC is subject to personal jurisdiction in Delaware because Avadel Specialty Pharmaceuticals, LLC has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel Specialty Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Avadel Specialty Pharmaceuticals, LLC manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel Specialty Pharmaceuticals, LLC is registered to do business in Delaware (business identification number 6507288) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

16. On information and belief, Avadel Legacy Pharmaceuticals, LLC is subject to personal jurisdiction in Delaware because Avadel Legacy Pharmaceuticals, LLC has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel Legacy Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Avadel Legacy Pharmaceuticals, LLC manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel Legacy Pharmaceuticals, LLC is registered to do

business in Delaware (business identification number 4886228) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

17. On information and belief, Avadel Management Corporation is subject to personal jurisdiction in Delaware because Avadel Management Corporation has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel Management Corporation is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Avadel Management Corporation manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel Management Corporation is registered to do business in Delaware (business identification number 6201113) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

18. On information and belief, Avadel CNS Pharmaceuticals LLC is subject to personal jurisdiction in Delaware because Avadel CNS Pharmaceuticals LLC has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel CNS Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Avadel CNS Pharmaceuticals LLC manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of

Delaware and, therefore, transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel CNS Pharmaceuticals LLC is registered to do business in Delaware (business identification number 7734658) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

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

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

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

The Patents-In-Suit

22. On May 20, 2014, the USPTO duly and lawfully issued the '963 patent entitled, "Sensitive Drug Distribution System and Method." A copy of the '963 patent is attached hereto as Exhibit A.

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

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

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

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

27. The claims of the patents-in-suit cover, *inter alia*, methods of use and administration of sodium oxybate or pharmaceutical compositions containing sodium oxybate. Jazz Pharmaceuticals owns the patents-in-suit.

Background

28. Jazz Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for sodium oxybate oral solution (NDA No. 21-196), which it sells under the trade name XYREM®. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '963 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to XYREM®.

29. Pursuant to its FDA-approved labeling, XYREM® is available only through a restricted distribution program called the XYWAV™ and XYREM® Risk Evaluation and

Mitigation Strategy ("REMS") because of the risks of central nervous system depression and abuse, misuse, and diversion.[1]

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

Acts Giving Rise to This Suit

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

32. On December 16, 2020, Avadel announced the submission of its NDA to the FDA. On information and belief, on February 26, 2021, the FDA notified Avadel of formal acceptance of Avadel's NDA with an assigned Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021.[2]

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

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

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

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

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

[3] *See id.*

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

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

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

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

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

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

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

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

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

44. On information and belief, Avadel has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Avadel's

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

Proposed Product prior to expiration of the patents-in-suit.[6] Avadel recently confirmed that is has "accelerated" its launch planning for its Proposed Product.[7]

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

Count I: Infringement of the '963 Patent

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

47. Avadel, by the submission of its NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel's Proposed Product, prior to the expiration of the '963 patent.

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

49. Avadel's submission of its NDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel's Proposed Product, prior to the expiration of the '963 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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

51. Avadel has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Avadel's Proposed Product prior to the expiration of the '963 patent.

52. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will infringe one or more claims of the '963 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States.

53. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will induce infringement of one or more claims of the '963 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, upon FDA approval of Avadel's NDA, Avadel will encourage acts of direct infringement with knowledge of the '963 patent and knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the '963 patent.

54. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will contributorily infringe one or more claims of the '963 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, Avadel has had and continues to have knowledge that Avadel's Proposed Product is especially adapted for a use that infringes one or more claims of the '963 patent and that there is no substantial non-infringing use for Avadel's Proposed Product.

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

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

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

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

Count II: Infringement of the '488 Patent

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

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

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

62. Avadel's submission of its NDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel's Proposed Product, prior to the expiration of the '488 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

64. Avadel has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Avadel's Proposed Product prior to the expiration of the '488 patent.

65. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will infringe one or more claims of the '488 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States.

66. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will induce infringement of one or more claims of the '488 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, upon FDA approval of Avadel's NDA, Avadel will encourage acts of direct infringement with knowledge of the '488 patent and knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the '488 patent.

67. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will contributorily infringe one or more claims of the '488 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, Avadel has had and continues to have knowledge that Avadel's Proposed Product is especially adapted for a use that infringes one or more claims of the '488 patent and that there is no substantial non-infringing use for Avadel's Proposed Product.

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

69. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Avadel's Proposed Product prior to expiration of

the ’488 patent by Avadel will constitute direct infringement, induced infringement, and/or contributory infringement of the ’488 patent.

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

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

Count III: Infringement of the ’885 Patent

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

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

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

75. Avadel’s submission of its NDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel’s Proposed Product, prior to the expiration of the ’885 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

77. Avadel has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Avadel’s Proposed Product prior to the expiration of the ’885 patent.

78. Unless enjoined by this Court, upon FDA approval of Avadel’s NDA, Avadel will infringe one or more claims of the ’885 patent under 35 U.S.C. § 271(a), including at least claim

1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States.

79. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will induce infringement of one or more claims of the '885 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, upon FDA approval of Avadel's NDA, Avadel will encourage acts of direct infringement with knowledge of the '885 patent and knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the '885 patent.

80. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will contributorily infringe one or more claims of the '885 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, Avadel has had and continues to have knowledge that Avadel's Proposed Product is especially adapted for a use that infringes one or more claims of the '885 patent and that there is no substantial non-infringing use for Avadel's Proposed Product.

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

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

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

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

Count IV: Infringement of the '956 Patent

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

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

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

88. Avadel's submission of its NDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel's Proposed Product, prior to the expiration of the '956 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

90. Avadel has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Avadel's Proposed Product prior to the expiration of the '956 patent.

91. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will infringe one or more claims of the '956 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States.

92. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will induce infringement of one or more claims of the '956 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, upon FDA approval of Avadel's NDA, Avadel will encourage acts of direct infringement with knowledge of the '956 patent and knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the '956 patent.

93. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will contributorily infringe one or more claims of the '956 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, Avadel has had and continues to have knowledge that Avadel's Proposed Product is especially adapted for a use that infringes one or more claims of the '956 patent and that there is no substantial non-infringing use for Avadel's Proposed Product.

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

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

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

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

Count V: Infringement of the '931 Patent

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

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

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

101. Avadel's submission of its NDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel's Proposed Product, prior to the expiration of the '931 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

103. Avadel has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Avadel's Proposed Product prior to the expiration of the '931 patent.

104. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will infringe one or more claims of the '931 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States.

105. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will induce infringement of one or more claims of the '931 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's

Proposed Product in the United States. On information and belief, upon FDA approval of Avadel's NDA, Avadel will encourage acts of direct infringement with knowledge of the '931 patent and knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the '931 patent.

106. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will contributorily infringe one or more claims of the '931 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, Avadel has had and continues to have knowledge that Avadel's Proposed Product is especially adapted for a use that infringes one or more claims of the '931 patent and that there is no substantial non-infringing use for Avadel's Proposed Product.

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

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

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

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

(C) An Order that the effective date of FDA approval of Avadel's NDA for its sodium oxybate drug product be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

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

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Avadel, its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from practicing any methods as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

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

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

(H) If Avadel engages in the commercial manufacture, use, sale, or offer for sale, or importation into the United States of Avadel's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Plaintiff resulting from such infringement, together with interest;

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

(J) Costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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