IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVADEL CNS PHARMACEUTICALS, LLC AND FLAMEL IRELAND LIMITED, Plaintiffs, v. JAZZ PHARMACEUTICALS, INC., AND JAZZ PHARMACEUTICALS IRELAND LIMITED, Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs Avadel CNS Pharmaceuticals, LLC and Flamel Ireland Limited (collectively, "Plaintiffs" or "Avadel"), by its attorneys, for its Complaint, allege as follows:

1. Avadel is a biopharmaceutical company focused on transforming medicines to help patients in need. Its approach includes applying innovative solutions to the development of medications that address the challenges patients face with current treatment options. Avadel has been achieving success with such reformulations for years, going back to a 2006 FDA approval of Flamel's controlled release blood pressure treatment, Coreg CR. One of Avadel's successes is its development of LUMRYZ™. LUMRYZ is an extended-release sodium oxybate medication approved by the FDA on May 1, 2023 as the first and only once-at-bedtime treatment for cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy.

2. Avadel's expertise and scientific research and development has resulted in Avadel being awarded multiple U.S. patents for its innovations. Defendants Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited's (collectively "Defendants" or "Jazz") are infringing – and inducing others to infringe – Avadel's patent rights by way of the importation, sale, offer for

sale, and promotion of Jazz's product XYWAV®, which is used for the treatment of, among other things, idiopathic hypersomnia.

3. This is an action for patent infringement under the Patent Act, 35 U.S.C. §§ *et seq.*, including 35 U.S.C. § 271, to obtain damages resulting from Jazz's infringement of at least one claim of Avadel's United States Patent Nos. 12,226,388 (the "'388 Patent") and 12,226,389 (the "'389 Patent") (collectively the "Patents-in-Suit").

PARTIES

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

5. Plaintiff Flamel Ireland Limited ("Flamel") is a limited company organized and existing under the laws of the Republic of Ireland and has its principal place of business at Ten Earlsfort Terrace, Dublin 2, D02 T380 Ireland.

6. On information and belief, 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.

7. On information and belief, Defendant Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, having a principal place of business at Waterloo Exchange, Waterloo Road, Dublin, Ireland 4.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Jazz Pharmaceuticals, Inc. because, upon information and belief, Jazz Pharmaceuticals, Inc. is a company organized and existing under the laws of Delaware and maintains a registered agent for service of process in Delaware, at 1209 Orange Street, Wilmington, Delaware, 19801. In addition, this Court has personal jurisdiction over Jazz Pharmaceuticals, Inc. because, on information and belief, Jazz Pharmaceuticals, Inc. regularly transacts business in Delaware, has derived substantial revenue from sales of pharmaceutical products in Delaware, and markets XYWAV in Delaware. On information and belief, Jazz Pharmaceuticals, Inc. has consented to jurisdiction in Delaware in one or more prior cases arising out of its manufacture, use, offer for sale, sale and/or importation of pharmaceutical products, including cases that it initiated as the plaintiff.

10. This Court has personal jurisdiction over Defendant Jazz Pharmaceuticals Ireland Limited because it 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, Jazz Pharmaceuticals Ireland Limited is in the business of, *inter alia*, developing, manufacturing, marketing, offering for sale, and selling pharmaceutical products including XYWAV throughout the United States, including within this District, either on its own or through its affiliates/subsidiaries. Therefore, Defendant Jazz Pharmaceuticals Ireland Limited transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

11. Further, to the extent personal jurisdiction does not exist over Jazz Pharmaceuticals Ireland Limited in Delaware, this Court has personal jurisdiction over it under Federal Rule of Civil Procedure 4(k)(2) because Jazz Pharmaceuticals Ireland Limited is not subject to jurisdiction

in any state's courts of general jurisdiction and exercising jurisdiction over it is consistent with the United States Constitution and laws.

12. Venue is proper in this District under 28 U.S.C. § 1400(b) with respect to Jazz Pharmaceuticals, Inc. at least because, on information and belief, Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware and therefore resides in Delaware for purposes of venue.

13. Venue is proper in this Court under 28 U.S.C. § 1391(c) with respect to Jazz Pharmaceuticals Ireland Limited, at least because, on information and belief, Jazz Pharmaceuticals Ireland Limited is not resident in the United States and may be sued in any judicial district.

THE PATENTS-IN-SUIT

14. The '388 Patent, entitled "Modified Release Gamma-Hydroxybutyrate Formulations Having Improved Pharmacokinetics" (Exhibit 1 hereto), was duly and legally issued on February 18, 2025. Flamel is the owner and assignee of the '388 Patent. Avadel CNS Pharmaceuticals, LLC is the exclusive licensee of the '388 Patent. The parties collectively hold all rights, title, and interest in and to the '388 Patent.

15. Claim 1 of the '388 Patent recites:

A method of treating a disorder treatable with a pharmaceutically acceptable salt of gamma-hydroxybutyrate in a human subject in need thereof, the method comprising:

orally administering a single nighttime daily dose to said human,

wherein said single nighttime daily dose comprises a first salt of gamma-hydroxybutyric acid and a second salt of gamma-hydroxybutyric acid,

wherein the first salt is selected from the group consisting of a sodium salt of gamma-hydroxybutyric acid, a calcium salt of gamma-hydroxybutyric acid, a potassium salt of gamma-hydroxybutyric acid, and a magnesium salt of gamma-hydroxybutyric acid,

wherein the second salt differs from the first salt and is selected from the group consisting of a sodium salt of gamma-hydroxybutyric acid, a calcium salt of gamma-

hydroxybutyric acid, a potassium salt of gamma-hydroxybutyric acid, and a magnesium salt of gamma-hydroxybutyric acid, and,

wherein the orally administering occurs only once nightly; and

uptitrating the single nighttime daily dose in increments equivalent to about 1.5 g of sodium oxybate per night at weekly intervals to effect.

16. The '389 Patent, entitled "Modified Release Gamma-Hydroxybutyrate Formulations Having Improved Pharmacokinetics" (Exhibit 2 hereto), was duly and legally issued on February 18, 2025. Flamel is the owner and assignee of the '389 Patent. Avadel CNS Pharmaceuticals, LLC is the exclusive licensee of the '389 Patent. The parties collectively hold all rights, title, and interest in and to the '389 Patent.

17. Claim 1 of the '389 Patent recites:

A method of treating a disorder treatable with a pharmaceutically acceptable salt of gamma-hydroxybutyrate in a human subject in need thereof, the method comprising:

orally administering a single nighttime daily dose to said human,

wherein said single nighttime daily dose comprises a first salt of gamma-hydroxybutyric acid and a second salt of gamma-hydroxybutyric acid,

wherein the first salt is selected from the group consisting of a sodium salt of gamma-hydroxybutyric acid, a calcium salt of gamma-hydroxybutyric acid, a potassium salt of gamma-hydroxybutyric acid, and a magnesium salt of gamma-hydroxybutyric acid,

wherein the second salt differs from the first salt and is selected from the group consisting of a sodium salt of gamma-hydroxybutyric acid, a calcium salt of gamma-hydroxybutyric acid, a potassium salt of gamma-hydroxybutyric acid, and a magnesium salt of gamma-hydroxybutyric acid, and,

wherein the single nighttime daily dose comprises an amount of salts of gamma-hydroxybutyric acid equivalent to 1.5 g, 3.0 g, 4.5 g, 6.0 g, 7.5 g, or 9.0 g of sodium oxybate,

wherein the orally administering occurs only once nightly and

wherein administration immediately after a high-fat meal results in a mean reduction in C_{max} of gamma-hydroxybutyrate by 33%.

JAZZ'S XYWAV PRODUCT

18. XYWAV is an oral solution that contains salts of gamma-hydroxybutyrate. It is administered orally.

19. According to the approved labeling for XYWAV, "XYWAV is a mixture of calcium oxybate, magnesium oxybate, potassium oxybate, and sodium oxybate (gamma-hydroxybutyrate)." Also according to the approved labeling, the inactive ingredients are purified water and sucralose. Also according to the approved labeling, each mL of XYWAV contains: 0.234 g calcium oxybate, $Ca(C_4H_7O_3)_2$; 0.096 g magnesium oxybate, $Mg(C_4H_7O_3)_2$; 0.13 g potassium oxybate, $K(C_4H_7O_3)$; and 0.04 g sodium oxybate, $Na(C_4H_7O_3)$ in dissociated form in the solution.

20. XYWAV's labeling states that it contains "a total salt concentration of 0.5 g per mL," which is the same total salt concentration of XYREM, Jazz's sodium salt oxybate product. XYWAV'S labeling further instructs patients transitioning from XYREM to XYWAV to begin treatment "the same dose (gram for gram)" as XYREM. Thus, a 3.0 g, 4.5 g, or 6.0 g dose of XYWAV is equivalent to 3.0 g, 4.5 g, or 6.0 g of sodium oxybate.

21. Jazz received approval from the FDA on August 12, 2021 to market and sell XYWAV for use in the treatment of Idiopathic Hypersomnia ("IH") in adults.[1]

22. XYWAV is also approved for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

[1] FDA, *Supplemental Approval* (Aug. 12, 2021), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/212690Orig1s006,021196Orig1s036ltr.pdf.

THE USE OF JAZZ'S XYWAV PRODUCT INFRINGES THE PATENTS-IN-SUIT

23. On information and belief, Jazz is currently marketing, manufacturing, distributing, using, offering for sale, selling, and/or importing XYWAV in the United States.[2] The approved labeling for XYWAV recites that it is "Distributed By: Jazz Pharmaceuticals, Inc. Palo Alto, CA 94304."[3]

24. On information and belief, under supplemental New Drug Application ("sNDA") No. 212690/S-006, Jazz has engaged and will engage in the commercial importation, offer for sale, use, and/or sale of XYWAV for use in the treatment of idiopathic hypersomnia.

25. XYWAV is being marketed and sold in the United States with a label including instructions for use as approved by FDA.

26. The XYWAV Prescribing Information provides instructions for administering XYWAV.

27. The XYWAV Prescribing Information encourages, recommends, instructs, and/or promotes administration of XYWAV to patients with disorders treatable with gamma-hydroxybutyrate, including idiopathic hypersomnia.

28. The XYWAV Prescribing Information recommends that in adult patients with idiopathic hypersomnia, "XYWAV can be administered as a twice or once nightly regimen in adults." For once-nightly dosing, the XYWAV Prescribing Information recommends: "Initiate dosage at 3 g or less per night orally, as one dose. Titrate to effect in increments of up to 1.5 g per night per week, up to 6 g total nightly dose." Jazz therefore encourages, recommends, instructs,

[2] FDA, Highlights of Prescribing Information, XYWAV (Apr. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/212690s011lbl.pdf (hereinafter "XYWAV Prescribing Information").
[3] *Id.*

and/or promotes the administration of XYWAV once-nightly orally at dosages between 1.5 g per night up to 6.0 g per night. Similarly, Jazz encourages, recommends, instructs, and/or promotes uptitrating the single nighttime daily dose in increments equivalent to about 1.5 g of sodium oxybate per night at weekly intervals to effect.

29. The XYWAV Prescribing Information states that "[a]dministration of XYWAV immediately after a high-fat meal resulted in a mean reduction in C_{max} of GHD by 33%." Jazz therefore encourages, recommends, instructs, and/or promotes the administration of XYWAV, wherein the administration after a high-fat meal results in a mean reduction in C_{max} of gamma-hydroxybutyrate by 33%.

30. Jazz markets XYWAV for use in treating at least the following symptoms of idiopathic hypersomnia: excessive daytime sleepiness, sleep inertial, cognitive impairment, and long sleep time. Jazz thus encourages, recommends, instructs, and/or promotes health care providers to prescribe XYWAV for use in a method of decreasing excessive daytime sleepiness in patients with idiopathic hypersomnia, and Jazz encourages, recommends, instructs, and/or promotes patients with idiopathic hypersomnia to take XYWAV as a method of decreasing excessive daytime sleepiness.[4]

31. Jazz's website includes promotional materials directed to the use of XYWAV for idiopathic hypersomnia, including a set of materials entitled "Now, IH Means I'm Here."[5] Those materials highlight that "XYWAV has been studied across several aspects of IH that may affect

[4] *See, e.g.*, Jazz Pharmaceuticals, *Xywav Idiopathic Hypersomnia (IH)*, https://www.xywav.com/idiopathic-hypersomnia (last visited Feb. 18, 2025); Jazz Pharmaceuticals, *What is XYWAV?*, https://www.xywav.com/idiopathic-hypersomnia/what-is-xywav (last visited Feb. 18, 2025).

[5] Jazz Pharmaceuticals, *NOW IH MEANS I'M HERE*, https://www.xywav.com/pdf/XYWAV_IH_Brochure.pdf (last visited Feb. 18, 2025).

you," and highlights "Excessive daytime sleepiness (EDS)." Jazz then promotes that in a clinical trial, "The average ESS score of people who continued XYWAV was 7 POINTS LESS than for people who stopped taking XYWAV—for significantly less daytime sleepiness."

32. The XYWAV Prescribing Information recommends to health care providers to "Advise the patient and/or caregiver to read the FDA-approved patient labeling (Medication Guide and Instructions for Use)." The XYWAV Medication Guide and Instructions for Use are a part of the XYWAV Prescribing Information. Jazz also links to the XYWAV Medication Guide and Instructions for Use on its website, www.xywav.com.[6] The Medication Guide instructs patients to read the XYWAV Medication Guide carefully and to read the Instructions for Use at the end of the Medication Guide for detailed instructions on how to take XYWAV.

33. The XYWAV Medication Guide instructs patients who have been prescribed XYWAV once-nightly to take "Take your XYWAV dose at bedtime . . . ." The Instructions for Use for once-nightly dosing instruct patients to "Drink all of the XYWAV dose while sitting in bed. Put the cap back on the pharmacy container and immediately lie down to sleep." The Instructions for Use provide step by step details of how to perform "1 time a night dosing."

DEFENDANTS' KNOWLEDGE OF THE PATENTS-IN-SUIT

34. Upon information and belief, Jazz is aware of the Patents-in-Suit at least because Jazz is aware of and monitors Avadel's patent portfolio. Jazz has admitted to regularly monitoring Avadel's patent filings. *See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, C.A. No. 21-691-GBW, D.I. 595 at 119-20, (D. Del. May 1, 2024) (testimony from P.J. Honerkamp, Jazz's Senior Vice President and Business Unit Head for the Sleep Business, "Q. Legal would monitor the

[6] *Medication Guide XYWAV®*, https://pp.jazzpharma.com/pi/xywav.en.MG.pdf (last visited Feb. 18, 2025).

patents Avadel was publishing? A. Yes."); *see also Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, C.A. No. 21-691-GBW, D.I. 597 at 692, (D. Del. May 1, 2024) (testimony from Phillip McGarrigle, Jazz's Senior IP Counsel, "Q. In your work at Jazz, do you have any responsibility for monitoring Avadel's patent portfolio? A. Yes."). Further, Jazz has repeatedly disclosed published Avadel patents and patent applications, including some related to the Patents-in-Suit, in Information Disclosure Statements ("IDS") with the U.S. Patent and Trademark Office ("USPTO") during the prosecution of its own patents. Jazz disclosed two Avadel U.S. patents and patent publications along with four Avadel international patents and publications[7] in an Information Disclosure Statement filed with the USPTO in Jazz's U.S. Patent Appl. No. 17/118,041 (which became U.S. Patent No. 11,077,079 (the "'079 patent")) on December 21, 2020. *See* '079 patent IDS filed Dec. 21, 2020; *see also* U.S. Patent No. 11,247,782 (the "'782 patent") IDS filed Mar. 30, 2021 (same); U.S. Patent No. 11,364,215 (the "'215 patent") IDS filed Apr. 9, 2021 (same). Jazz disclosed fifteen additional Avadel U.S. patents and patent publications along with two additional Avadel international patent publications[8] in Information Disclosure Statements filed with the USPTO in Jazz's '079 patent, '782 patent, and '215 patent on April 27, 2021. *See* '079 patent IDS filed Apr. 27, 2021; '782 patent IDS filed Apr. 27, 2021; '215 patent IDS filed Apr. 27, 2021. During the prosecution of recent patent applications, Jazz disclosed eighteen Avadel U.S. patents and patent publications along with six international patents and

[7] Jazz disclosed: U.S. Patent No. 10,272,062; U.S. Patent Pub. No. 2018/0021284; European Patent Nos. 0709087 and 1434572; International Patent Pub. Nos. WO 2005/099671 and WO 2018/015563.

[8] Jazz disclosed: U.S. Patent Nos. 10,736,866; 10,952,986; 10,973,795; and 10,925,844; U.S. Patent Pub. Nos. 2019/0183806; 2019/0183836; 2019/0269640; 2019/0269641; 2019/0274990; 2019/0282532; 2020/0197347; 2020/0276142; 2020/0360293; 2020/0360319; 2020/0368187; International Patent Pub. Nos. WO 2019/123269 and WO 2020/178695.

patent publications[9] in Information Disclosure Statements filed with the USPTO. *See* U.S. Patent Appl. No. 17/860,498 IDS filed Sept. 5, 2024; U.S. Patent Appl. No. 18/699,363 IDS filed Oct. 18, 2024; U.S. Patent Appl. No. 18/652,039 IDS filed July 1, 2024.

35. The Patents-in-Suit are related to U.S. Patent Nos. 10,272,062; 10,736,866; and 11,065,224 and Avadel's U.S. Patent Pub. Nos. 2018/0021284; 2019/0183836; and 2020/019734, each independently disclosed in multiple Jazz Information Disclosure Statements.

36. The application leading to the '388 Patent, U.S. Appl. No. 18/758,699, became public on November 14, 2024, as U.S. Publication No. 2024/0374549. The final claims and corrected notice of allowance of the '388 Patent became public as of December 20, 2024. The fact that the '388 Patent would issue became public as of the December 20, 2024 corrected issue fee payment.

37. Given Jazz's pattern and practice of closely monitoring Avadel's patent application publications as set forth above, and given the public disclosure of the claims of the '388 Patent on November 14, 2024 and the disclosure that the corrected issue fee was paid on December 20, 2024 date, Avadel alleges, on information and belief, that Jazz has been aware of the claims of the '388 Patent since at least December 20, 2024.

38. Further, the application leading to the '389 Patent, U.S. Appl. No. 18/759,364, became public on November 7, 2024, as U.S. Publication No. 2024/0366547. The final claims and corrected notice of allowance of the '389 Patent became public as of December 20, 2024. The

[9] Jazz disclosed: U.S. Patent Nos. 10,272,062; 10,736,866; 10,952,986; 10,973,795; 10,925,844; 11,065,224; U.S. Patent Pub. Nos. 2018/0021284; 2019/0183806; 2019/0183836; 2019/0269640; 2019/0269641; 2019/0274990; 2019/0282532; 2020/0197347; 2020/0276142; 2020/0360293; 2020/0360319; 2020/0368187; European Patent Nos. EP 0709087 and 1434572; International Patent Pub. Nos. WO 2005/099671; WO 2018/015563; WO 2019/123269; WO 2020/178695.

fact that the ’389 Patent would issue became public as of the December 20, 2024 corrected issue fee payment.

39. Similarly given Jazz’s pattern and practice of closely monitoring Avadel’s patent application publications as set forth above, and given the public disclosure of the claims of the ’389 Patent on November 7, 2024 and the disclosure that the corrected issue fee was paid on December 20, 2024, Avadel alleges, on information and belief, that Jazz has been aware of the claims of the ’389 Patent since at least December 20, 2024.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 12,226,388

40. Avadel incorporates each of the preceding paragraphs as if fully set forth herein.

41. On information and belief, Jazz is marketing and selling XYWAV in the United States with the XYWAV Prescribing Information (which includes the XYWAV Medication Guide and Instructions for Use). Through at least those documents, its marketing campaign, and its websites, including https://www.xywav.com/idiopathic-hypersomnia, Jazz encourages, recommends, instructs, and/or promotes health care providers to prescribe and patients to take XYWAV for use in a method of treating a disorder treatable with gamma-hydroxybutyrate by orally administering XYWAV comprising salts of gamma-hydroxybutyrate equivalent to 3.0 g, 4.5 g, or 6.0 g of sodium oxybate only once nightly at bedtime at least two hours after eating uptitrating the single nighttime daily dose in increments equivalent to about 1.5 g of sodium oxybate per night at weekly intervals to effect.

42. Health care providers and/or patients directly infringe, literally or under the doctrine of equivalents, at least claim 1 of the ’388 Patent when patients are instructed to and do take XYWAV once-nightly for idiopathic hypersomnia in the manner instructed, taught, encouraged, and/or suggested by Jazz through the XYWAV Prescribing Information (which

includes the XYWAV Medication Guide and Instructions for Use) and Jazz's marketing materials, including Jazz's websites. Health care providers and/or patients have infringed and will continue to infringe by prescribing and/or using XYWAV in this manner.

43. Jazz indirectly infringes at least claim 1 of the '388 Patent by, without authorization from Avadel, actively encouraging, instructing, and inducing others to use or practice in the United States infringing methods of treatment as set forth herein.

44. Jazz has actively induced infringement under 35 U.S.C. § 271(b), and will continue to actively induce infringement, of at least claim 1 of the '388 Patent by way of the substance of the XYWAV Prescribing Information (which includes the XYWAV Medication Guide and Instructions for Use) and/or by way of its marketing of XYWAV.

45. On information and belief, despite Jazz's knowledge of the '388 Patent, Jazz is proceeding with its infringing activity, and with the specific intent to cause (or willful blindness to causing) infringement of the '388 Patent by others as set forth herein.

46. On information and belief, Jazz has no reasonable basis for believing that it would not be liable for infringing the '388 Patent or believing that '388 Patent is invalid or otherwise unenforceable.

47. Jazz's infringement of the '388 Patent is willful.

48. Avadel has suffered and will suffer monetary damages as a result of Jazz's infringement of the '388 Patent.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 12,226,389

1. Avadel incorporates each of the preceding paragraphs as if fully set forth herein.

2. On information and belief, Jazz is marketing and selling XYWAV in the United States with the XYWAV Prescribing Information (which includes the XYWAV Medication Guide and Instructions for Use). Through at least those documents, its marketing campaign, and its

websites, including https://www.xywav.com/idiopathic-hypersomnia, Jazz encourages, recommends, instructs, and/or promotes health care providers to prescribe and patients to take XYWAV for use in a method of treating a disorder treatable with gamma-hydroxybutyrate by orally administering XYWAV comprising salts of gamma-hydroxybutyrate equivalent to 3.0 g, 4.5 g, or 6.0 g of sodium oxybate only once nightly at bedtime at least two hours after eating, where administration of XYWAV immediately after a high-fat meal results in a mean reduction in C_{max} of gamma-hydroxybutyrate by 33%.

3. Health care providers and/or patients directly infringe, literally or under the doctrine of equivalents, at least claim 1 of the ’389 Patent when patients are instructed to and do take XYWAV once-nightly for idiopathic hypersomnia in the manner instructed, taught, encouraged, and/or suggested by Jazz through the XYWAV Prescribing Information (which includes the XYWAV Medication Guide and Instructions for Use) and Jazz’s marketing materials, including Jazz’s websites. Health care providers and/or patients have infringed and will continue to infringe by prescribing and/or using XYWAV in this manner.

4. Jazz indirectly infringes at least claim 1 of the ’389 Patent by, without authorization from Avadel, actively encouraging, instructing, and inducing others to use or practice in the United States infringing methods of treatment as set forth herein.

5. Jazz has actively induced infringement under 35 U.S.C. § 271(b), and will continue to actively induce infringement, of at least claim 1 of the ’389 Patent by way of the substance of the XYWAV Prescribing Information (which includes the XYWAV Medication Guide and Instructions for Use) and/or by way of its marketing of XYWAV.

6. On information and belief, despite Jazz's knowledge of the '389 Patent, Jazz is proceeding with its infringing activity, and with the specific intent to cause (or willful blindness to causing) infringement of the '389 Patent by others as set forth herein.

7. On information and belief, Jazz has no reasonable basis for believing that it would not be liable for infringing the '389 Patent or believing that the '389 Patent is invalid or otherwise unenforceable.

8. Jazz's infringement of the '389 Patent is willful.

9. Avadel has suffered and will suffer monetary damages as a result of Jazz's infringement of the '389 Patent.

JURY TRIAL DEMAND

10. Avadel hereby demands a trial by jury on all issues triable as such.

PRAYER FOR RELIEF

WHEREFORE, Avadel requests the following relief:

(a) entry of judgment that Jazz infringes and will infringe the Patents-in-Suit;

(b) an award of damages, not less than a reasonable royalty, sufficient to compensate Avadel for infringement of the Patents-in-Suit, together with pre- and post-judgment interests and costs as fixed by the Court pursuant to 35 U.S.C. § 284;

(c) entry of an order compelling Jazz to compensate Avadel for any ongoing or future infringement of the Patents-in-Suit, in an amount and terms appropriate for the circumstances;

(d) entry of an order that Jazz's infringement has been willful, and increased damages pursuant to 35 U.S.C. § 284;

(e) a declaration that this patent infringement case is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) an award of Avadel's costs and expenses in this action; and

(g) such further and other relief as this Court may deem just and proper.

Dated: February 18, 2025

MCCARTER & ENGLISH, LLP

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