IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-691-GBW [redacted]
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1138-GBW [redacted]
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1594-GBW [redacted]

DEFENDANT'S OPENING BRIEF IN SUPPORT OF EMERGENCY MOTION FOR STAY PENDING APPEAL

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

I. INTRODUCTION AND BACKGROUND

Defendant Avadel CNS Pharmaceuticals, LLC (Avadel) respectfully disagrees with, and has appealed from, this Court's August 27 Order (Order) granting Plaintiff Jazz Pharmaceuticals, Inc.'s (Jazz's) motion for limited permanent injunction. That injunction overlooks a crucial feature of federal patent law, under which it "shall not be an act of infringement" to "use" a "patented invention" if such use is "reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1). That safe-harbor provision protects any use of a patented invention that is "reasonably related to [the] FDA approval" process. *See Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997). During this Court's June 4 hearing on Jazz's motion for injunction, counsel for Avadel emphasized this feature of the patent laws and explained that as to "conduct" that is "intended to generate data for submission to FDA," there is "nothing to [e]njoin," since such conduct is non-infringing. Ex. A (Injunction Hrg. Tr.) at 66, 77. This Court agreed, affirmatively recognizing that such conduct is "protected by statute." *Id.* at 67.

Yet this Court's injunction prohibits Avadel from engaging in conduct that is expressly protected by statute. By its terms, it prevents Avadel from "seek[ing] approval of [LUMRYZ] from the FDA for the treatment of IH," or idiopathic hypersomnia. D.I. 666 (C.A. No. 21-691) at 3.[1] And while the Order permits Avadel to "continue to use [LUMRYZ] in currently-ongoing clinical trials," it bars Avadel from undertaking any future clinical trials for IH patients. *Id.* It therefore prohibits Avadel from undertaking the kind of "development and submission of information" that the patent laws specifically protect. 35 U.S.C. § 271(e)(1). For this reason,

[1] All docket references in this brief refer to docket entries in C.A. No. 21-691.

Avadel believes that the injunction issued by this Court is overbroad and believes the Federal Circuit will agree.

Avadel now presents this motion for stay pending appeal because, in the days since the Court issued its injunction, Jazz has made clear that it will seek to construe the Order in a manner that is contrary to both its plain terms and in a manner that is plainly at odds with both the statutory authority to enjoin infringement and with the unambiguous import of the safe harbor. In particular, Jazz recently informed Avadel that it will seek to enforce that injunction to disrupt Avadel's *ongoing* clinical-trial for IH and Avadel's *already-pending* FDA submission regarding pediatric *narcolepsy* patients, even though the injunction exempted those activities.

Shortly after Avadel filed its notice of appeal, Avadel's counsel wrote to Jazz's counsel, proposing a schedule for expedited appellate briefing. Avadel's letter also noted that, "on July 31, 2024, Avadel publicly announced that the first patient had been dosed in REVITALYZ, a Phase 3 clinical study evaluating LUMRYZ as a potential treatment for IH." Ex. B (Avadel Letter) at 1. As Avadel explained, the study "will enroll approximately 150 adults who are diagnosed with IH and includes an open label extension portion," whereby "patients who enroll in the ongoing IH trial may continue to receive treatment pursuant to current or future open label extensions." *Id.* at 1-2. Avadel asked for Jazz's view of "the scope of the Injunction Order." *Id.*

Jazz responded on the evening of Friday, August 30, broadly asserting that any continued work on Avadel's IH clinical study is proscribed by this Court's injunction. Jazz stated: "Avadel is enjoined from seeking FDA approval for IH[;] the safe harbor would not apply to activities for that indication." Ex. C (Jazz Letter) at 2. Jazz asked Avadel to "confirm" that Avadel "will not take any further action" as to IH clinical studies, including "conducting further clinical trials such as enrolling additional subjects in ongoing studies and beginning any proposed open label

extension of any ongoing study." *Id.* And it even demanded that Avadel "confirm" that pursuant to the injunction it had "withdrawn" its FDA application for approval of LUMRYZ for the "treatment of pediatric patients with narcolepsy." *Id.*[2]

In light of Jazz's letter, it is now clear that, if this Court's injunction remains in effect while Avadel appeals, Jazz will try to use it to seriously and immediately impair Avadel's ongoing IH clinical trial work and its prior request for pediatric approval for narcolepsy patients. The ongoing clinical trial (called the REVITALYZ trial) is exempt from the Order and otherwise immune from any claim of infringement per the plain terms of the safe harbor. As to pediatric narcolepsy, the mere maintenance of a request to the FDA is likewise not an act of infringement that can be enjoined; it is not a statutory act of infringement within the ambit of 35 U.S.C. § 271(a). And even if it were, it would be exempt pursuant to the safe harbor of § 271(e)(1). Jazz's strained reading of the Order thus threatens Avadel with imminent and irreparable harm. The public, too, would be at risk. Congress added the statutory safe harbor precisely to allow clinical trials and other activities for seeking FDA approval to continue despite existing patents, placing new treatments in a position for FDA approval as soon as possible. Conversely, staying the injunction pending appeal will not harm Jazz.

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[2] Avadel submitted its FDA application for pediatric narcolepsy patients on November 7, 2023—long before the injunction issued—and Avadel expects that FDA approval for pediatric narcolepsy could be issued within days. *See Avadel Pharmaceuticals Provides Corporate Update and Reports Fourth Quarter and Full Year 2023 Financial Results* (Mar. 4, 2024), https://investors.avadel.com/node/13741/pdf (noting "FDA target action date of September 7, 2024); *Avadel Pharmaceuticals Provides Corporate Update and Reports Third Quarter 2023 Financial Results* (Nov. 8, 2023) (noting November 7, 2023 submission to FDA). The injunction does not require Avadel to "withdraw" any previously submitted applications to FDA, and indeed expressly provides that Avadel is *not* barred from "making, using, and selling" LUMRYZ for "the treatment of narcolepsy." D.I. 666 at 2. The Court specifically ruled that "Jazz's request for a limited permanent injunction prohibiting the use of [LUMRYZ] for new patients in the narcolepsy market is denied." *Id.* at 1. Consistent with the plain terms of the injunction, Avadel is entitled to market LUMRYZ to pediatric narcolepsy patients upon receipt of FDA approval.

Avadel therefore respectfully seeks a stay of the injunction pending appeal.

II. LEGAL STANDARD

Four factors govern the issuance of a stay pending appeal: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Nken v. Holder*, 556 U.S. 418, 434 (2009) (citation omitted).

III. ARGUMENT

A. Avadel Is Likely To Succeed On The Merits Of Its Appeal

Avadel respectfully submits that it is likely to succeed on the merits of its challenge to this Court's injunction. The injunction prohibits Avadel from (1) conducting future clinical trials in order to develop information about the efficacy and safety of LUMRYZ for IH patients (and other potential uses); and (2) submitting that information to FDA as part of an application for approval from that agency. The Patent Act's safe harbor expressly classifies both of those things as non-infringing: it is "*not* … an act of infringement" for activities "reasonably related to the *development* and *submission* of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1) (emphasis added). There is no basis to enjoin that non-infringing conduct.

Moreover, Jazz's strained reading of the injunction would supposedly have Avadel "withdraw" its long-pending request for pediatric narcolepsy, but the Court denied in its entirety Jazz's motion "for a limited permanent injunction prohibiting the use of [LUMRYZ] for new patients in the narcolepsy market" (D.I. 665 at 1), and Avadel's maintenance of such a request is both within the safe harbor and conduct protected under the First Amendment. Jazz's corollary

assertion that Avadel should have to freeze enrollment in the ongoing IH clinical trial is likewise contrary to the plain language of the Order and the statutory safe harbor.

1. Avadel Is Likely To Defeat Jazz's Strained Reading Of The Injunction With Regard To Pediatric Narcolepsy

Avadel is likely to succeed in establishing that Jazz's view of the scope of the injunction with regard to pediatric narcolepsy is erroneous. Avadel long ago requested that the FDA permit LUMRYZ to be administered to pediatric patients suffering from narcolepsy, and Jazz elicited testimony at trial regarding that request. D.I. 596 (517:13-518:16). Following trial, Jazz made the tactical decision to seek an injunction that would have prohibited LUMRYZ from being made, used, or sold for ***any*** future narcolepsy patients—which necessarily included the pediatric population that is the subject of Avadel's pending request to FDA. The Court ruled, however, that "Jazz's request for a limited permanent injunction prohibiting the use of [LUMRYZ] for new patients in the narcolepsy market is **DENIED**" (D.I. 665 at 1), concluding that "[w]ith respect to the market for narcolepsy … Jazz has not shown that it is entitled to an injunction restraining the use or sale of [LUMRYZ] for new narcolepsy patients." *Id*. at 2. Consistent with that ruling, the Order contains an express exemption for "making, using, and selling [LUMRYZ]: (a) for the treatment of narcolepsy." D.I. 666 at 1. Further, the terms of the Order are purely prospective (addressing future conduct in that Avadel "may not seek" additional indications) and prohibitory rather than mandatory; nowhere in the Order does the Court require Avadel to undertake the affirmative action of *withdrawing* its prior request to the FDA for pediatric approval for narcolepsy. *See* D.I. 666.

Again, Jazz was well aware of Avadel's pending request for FDA approval with respect to pediatric narcolepsy request when it filed its injunction papers, and Jazz made no attempt to demonstrate irreparable harm with regard to any proposed injunction that would have required

Avadel to withdraw its pending pediatric narcolepsy request. *See* D.I. 587; D.I. 610. Thus, Jazz plainly failed to establish its entitlement to an injunction as broad as it now pretends.

But Jazz's pretense threatens imminent and irreparable harm to Avadel. Avadel is due to receive a decision from the FDA on its request on September 7, 2024. *See supra* p.3 n.2. And Avadel fully expects that the FDA will grant its request. Pediatric narcolepsy patients are narcolepsy patients, and FDA has already determined that LUMRYZ offers a meaningful contribution to patient care given its once-nightly dosing, which is particularly significant in pediatric care, where parents may need to wake along with the pediatric patient to supervise the middle-of-the-night dose from Jazz's oxybate salt treatments. *See* D.I. 608 at 10-11 (Lavender Decl. ¶ 17). And Jazz appears to be threatening to seek "contempt" against Avadel unless it accedes to Jazz's view of the scope of the Order. Ex. C (Jazz Letter) at 2 n.1.

Jazz's view of the scope of the order—were it accepted—would not only contradict the Order on its face, but it would also sweep far beyond the relief to which Jazz could possibly be entitled. Courts have the power to enjoin future ***acts of infringement***:

> [T]he only acts the injunction may prohibit are ***infringement of the patent*** by the adjudicated devices and infringement by devices not more than colorably different from the adjudicated devices. In order to comply with Rule 65(d), the injunction should explicitly proscribe only those specific acts.

Int'l Rectifier Corp. v. IXYS Corp., 383 F.3d 1312, 1316 (Fed. Cir. 2004) (emphasis added). Per the plain language of the statute, infringement is confined to one who "makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent." 35 U.S.C. § 271(a). Merely maintaining a prior FDA request for pediatric approval for narcolepsy is none of those things; it is merely maintaining a request that the FDA permit approval for that population. And to the extent that Jazz claims

(erroneously) that maintaining a prior request to the FDA concerning narcolepsy is a "use," any such "use" would fall squarely within the safe harbor of § 271(e)(1). That safe harbor "provides a wide berth for the use of patented drug in activities related to the federal regulatory process." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005). In addition, Avadel has a constitutional right to maintain its request to the FDA concerning pediatric narcolepsy. "The right of petition is one of the freedoms protected by the Bill of Rights," and that right protects "the approach of citizens or groups of them to administrative agencies." *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972). Jazz's extreme reading of the Order would thus impermissibly impinge on Avadel's protected right to maintain its pending petition to the FDA.

2. This Court's Injunction Goes Too Far In Enjoining Avadel's Non-Infringing Efforts To Seek FDA Approval For An IH Indication

An injunction may be entered against a defendant only "on account of a harm resulting from the defendant's wrongful conduct, not some other reason." *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 640 (Fed. Cir. 2015). And a district court's power to grant injunctive relief "to prevent violation of patent rights" does not extend to conduct that is entirely "non-infringing." *Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc.*, 986 F.2d 476, 479-80 (Fed. Cir. 1993). Yet the injunction here bars conduct relating to seeking FDA approval for an IH indiciation that is entirely non-infringing.

By its terms, the injunction prohibits Avadel from "seek[ing] approval of [LUMRYZ] from the FDA for the treatment of IH," and from using [LUMRYZ] in connection for any approval process, except with respect to "currently-ongoing clinical trials and studies." D.I. 666 at 2-3. Thus, the injunction prohibits Avadel from either undertaking any new IH clinical studies or submitting the results of any IH clinical studies (ongoing or new) to FDA pursuant to FDA's regulatory approval process. But those enjoined activities are non-infringing as a matter of clear

statutory law, which specifically provides a safe harbor: as discussed, it "shall not be an act of infringement" to "use" a "patented invention" if such use is "reasonably related to the *development* and *submission* of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1) (emphasis added). The safe harbor expressly protects activities that the Court's injunction prohibits.

First, a prohibition on IH clinical trials flatly contradicts the Patent Act's safe-harbor protection for uses "reasonably related to the development" of information for FDA approval of a new drug product. It has long been recognized that this provision categorically protects clinical trials, *see Merck*, 545 U.S. at 202 n.6, including all uses "reasonably related to recruiting [assistance] for a clinical trial to support FDA approval," as the Federal Circuit recently reiterated. *Edwards Lifesciences Corp. v. Meril Life Sci. Pvt. Ltd.*, 96 F.4th 1347, 1351 (Fed. Cir. 2024). Indeed, Congress instituted the safe harbor in 1984 precisely to protect clinical trials and other "activities necessary to obtain regulatory approval." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990) ("This [safe harbor] allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval."). The injunction cannot be squared with the statutory safe harbor.

Second, the Patent Act provides that seeking FDA approval is not infringing activity. Indeed, the submission of clinical-trial information to FDA does not qualify as the "use[ ]" of a "patented invention," and therefore does not qualify as infringement in the first instance. 35 U.S.C. § 271(a). And if there were any doubt on that score, the safe harbor dispels it: "uses reasonably related to the … submission of information" to the FDA are non-infringing. *Id.* § 271(e)(1). An application for FDA approval *is* a "submission of information" to the FDA, so it is necessarily non-infringing. *See Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997) (safe harbor

protects any "use … reasonably related to FDA approval"). That reading is also informed by deep-rooted constitutional principles: Avadel has a First Amendment right to petition "administrative agencies" like the FDA, and it would be "destructive of" that right to prohibit Avadel from advocating its "points of view" with the FDA. *Cal. Motor Transp.*, 404 U.S. at 510. A construction of Section 271(e)(1) that permitted this Court to enjoin Avadel from seeking FDA approval of a drug would raise serious constitutional problems.

Jazz's recent assertions concerning the purported scope of the Order are particularly pernicious and contrary to both the plain language of the Order and the plain import of the safe harbor. Thus, Jazz insists that the Order somehow obligates Avadel to "not take any further action, including … enrolling additional subjects in ongoing studies and beginning any proposed open label extension of any ongoing study." Ex. C (Jazz Letter) at 2. But as Jazz is aware, on July 31, 2024, Avadel publicly announced that the first patient had been dosed in REVITALYZ, a Phase 3 study evaluating LUMRYZ as a potential treatment for IH. Ex. B (Avadel Letter) at 1. As Avadel announced at the time, "[t]he study will enroll approximately 150 adults who are diagnosed with IH and includes an open label extension portion." *Id*.

While Avadel acknowledges that the Court was not aware of the REVITALYZ clinical trial during briefing or argument on Jazz's Motion for Permanent Injunction because it was not yet initiated at that time, the fact remains that as of August 27, 2024, it was a "currently-ongoing clinical trial[]" within the ambit of the exemption set forth in Section 1(A)(c) of the Order. *See* Dkt. 666 at 2; *see also* ClinicalTrials.gov, *Safety and Efficacy of FT218 in Idiopathic Hypersomnia*, https://clinicaltrials.gov/study/NCT06525077?term=NCT06525077&rank=1 (last updated July 29, 2024) ("This is a double-blind, placebo-controlled, randomized withdrawal, multicenter study of the efficacy and safety of FT218 with an open-label safety extension period.

… The study will enroll subjects who are diagnosed with idiopathic hypersomnia. Subjects will be eligible to enroll regardless of current treatment with oxybate therapy or stimulants/alerting agents at study entry.").

Avadel is likely to succeed in establishing that Jazz's view of the scope of the injunction is erroneous. Jazz appears to suggest that the exemption is limited to clinical trial patients that were already prescribed LUMRYZ in the REVITALYZ study as of August 27, 2024. *See* Ex. C (Jazz Letter) at 2. But such activity is already exempted from the scope of the Order pursuant to Section 1(A)(b). *See* D.I. 666 at 2. Thus, Jazz's reading of the Order would render Section 1(A)(c), *see id.*, entirely superfluous, which is plainly wrong.

Further, Jazz's view of the scope of the exemption would place it in conflict with the plain language of the safe harbor of § 271(e)(1). Again, clinical studies fall comfortably within the safe harbor, which "provides a wide berth for the use of patented drug in activities related to the federal regulatory process." *Merck*, 545 U.S. at 202. As the Federal Circuit recently explained, "it is apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to ***all uses*** of patented inventions that are reasonably related to the development and submission of *any* information under the Federal Food, Drug, and Cosmetic Act." *Edwards Lifesciences*, 96 F.4th at 1351 (quoting *Merck*, 545 U.S. at 202) (emphasis added). Indeed, the Federal Circuit recently emphasized that "[m]ooring in the safe harbor is available to defendants irrespective of the stage of research and ***even if the information is never ultimately submitted to the FDA***." *Id.* (emphasis added). The entirety of the REVITALYZ study falls within the scope of the safe harbor, and Jazz's apparent view of the Order clearly conflicts with the statute.

3. Neither The Equities Nor The Public Interest Support The Injunction

Avadel is also likely to succeed on appeal because this Court's findings concerning the equities and the public interest did not match the scope of the injunction. For instance, this Court

found that LUMRYZ's "entrance into the market for IH would irreversibly harm Jazz's market share and damage its ability to build its reputation as the exclusive market leader." D.I. 665 at 22. It therefore held that "Jazz would suffer irreparable injury if Avadel is not enjoined from seeking FDA approval and marketing [LUMRYZ] for IH." *Id.* But that does not follow. Even accepting for the sake of argument this Court's findings regarding the irreparable harm Jazz might suffer if Avadel were to *market* LUMRYZ to IH patients following FDA approval, that does not establish Jazz would suffer irreparable harm merely because Avadel *conducts additional trials* on IH and *seeks FDA approval* to market LUMRYZ to IH patients. This Court made no findings establishing that conducting clinical trials or submitting an application for FDA approval would irreparably harm Jazz. And the Court's analysis of the balance of the equities similarly lacks any justification for enjoining such activities. *Id.* at 25.

Likewise, the Court's public-interest analysis incorrectly presumes that the public would not be harmed. That determination preempts the FDA's role in considering the efficacy and potential clinical superiority of LUMRYZ vis-à-vis other IH drugs. *See id.* at 25-29. It is not possible to analyze the public interest in the market availability of LUMRYZ for IH patients without first giving the FDA the chance to review the scientific evidence. But that is what the injunction forbids.

B. Avadel Will Suffer Irreparable Harm In The Absence Of A Stay

Not only is Avadel is likely to succeed on the merits of its appeal, but absent a stay, the injunction will irreparably harm Avadel by restraining statutorily protected research regarding IH and prohibiting Avadel from seeking an IH indication for LUMRYZ. As explained by Dr. Jennifer Gudeman, Avadel's Vice President for Medical and Clinical Affairs, the injunction imposes several immediate (and irreparable) practical harms. *See* Gudeman Decl.

First, the injunction—notwithstanding its carveout for any "ongoing" clinical trial—presents a serious risk of impairing Avadel's recently commenced REVITALYZ trial, which is Avadel's first step towards supporting an eventual application for an IH indication for Lymryz. *Id.* at ¶ 4. Thus, even though Avadel is likely to prevail on appeal, it will (absent a stay) suffer irreparable harm with respect to its ongoing clinical trial while its appeal is pending. To complete its clinical trial, Avadel must enroll a sufficient number of IH patients, and Avadel has not yet done so. *Id.* ¶ 5. And concerns over legal impediments to clinical trials can damage the confidence of physicians who would otherwise recommend that their patients enroll. *Id.* ¶¶ 9-10. Physicians who become aware of the injunction may have concerns that the study may be interrupted or end early, which makes recruitment more difficult. *Id.* Thus, the injunction presents a substantial risk of disrupting the ongoing REVITALYZ trial, or at least delaying its progress. Every day that the REVITALYZ trial is delayed as a result of the injunction is a form of irreparable harm to Avadel's reputation and one of its core business objectives: to place LUMRYZ on the market for IH patients as quickly as possible, and to demonstrate LUMRYZ's efficacy and safety for IH patients. *Id.* And that harm does not encompass the further harm that Avadel will encounter if it needs to undertake further clinical studies of LUMRYZ and is prevented from doing so by the plain terms of the district court's injunction. *Id.* ¶¶ 10-11.

Indeed, the Order creates harm of a sort that the Supreme Court emphasized is precisely of the type that the safe harbor of § 271(e)(1) was enacted to address—the effective and improper extension of any alleged patent term to which Jazz claims entitlement:

> In 1984, the Court of Appeals for the Federal Circuit decided that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement, *see* 35 U.S.C. § 271(a), even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval. Since that activity could not be commenced by those who planned to compete with the patentee until expiration of the entire patent term, the patentee's

> *de facto* monopoly would continue for an often substantial period until regulatory approval was obtained. In other words, the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term. The 1984 Act sought to eliminate this distortion ….
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> § 202 of the Act … added to the provision prohibiting patent infringement, 35 U.S.C. § 271, the paragraph at issue here, establishing that "[i]t shall not be an act of infringement to make, use, or sell a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1). This allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval.

Lilly, 496 U.S. at 670-71.

Second, Avadel's harm is all the more clear and pressing in light of Jazz's view on the scope of the injunction. Jazz now asserts that the injunction prohibits Avadel from even enrolling new IH patients in its ongoing clinical study or continuing any "open label extension" for currently enrolled study participants. Ex. C (Jazz Letter) at 2. That is a clear misreading of the injunction's scope, which expressly exempts "ongoing" clinical trials. But Jazz is threatening Avadel with contempt if Avadel does not comply with Jazz's inflated view of the injunction. That could mean the end of Avadel's current clinical trial. Halting enrollment in the REVITALYZ trial would pose irreparable harms to Avadel's reputation with researchers and patients, and would significantly and irreparably delay the progress of the REVITALYZ trial. Gudeman Decl. at ¶¶ 6-9. And open label extensions—which allow clinical-trial participants to continue using a trial drug following completion of the monitored phase of the clinical trial—are a part of the clinical trial itself and a "valuable recruiting tool" for boosting enrollment in clinical trials. *Id.* at ¶ 10. They fall squarely within the scope of the statutory safe harbor, since they are "reasonably related to recruiting [assistance] for a clinical trial to support FDA approval." *Edwards Lifesciences*, 96 F.4th at 1351. If the injunction prohibited open label extensions, that too would "result in irreparable harm to Avadel." Gudeman Decl. at ¶ 10.

Furthermore, Jazz also insists that the injunction requires Avadel to affirmatively withdraw its *already-pending* application for FDA approval of LUMRYZ for pediatric narcolepsy patients. Ex. C (Jazz Letter) at 2. That, too, is contrary to the injunction's text, which does not apply to narcolepsy and does not require withdrawal of any FDA submissions. Moreover, as discussed, seeking FDA approval falls squarely in the safe harbor. But once more Jazz's extreme position threatens contempt and irreparable harm.

Third, the injunction treads on Avadel's First Amendment right to petition the FDA—and that injury is irreparable per se. A "loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Kim v. Hanlon*, 99 F.4th 140, 159 (3d. Cir. 2024) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). This Court should issue a stay pending appeal so that these clear, immediate, and irreparable harms to Avadel are averted.

C. A Stay Pending Appeal Will Not Harm Jazz

Whereas the denial of a stay will inflict irreparable harms on Avadel, Jazz cannot assert that it will suffer any harm (irreparable or otherwise) from the issuance of a stay pending appeal. [redacted] *See* Gudeman Decl. at ¶ 11. Avadel's pending appeal is sure to be resolved well before then, particularly in light of the accelerated briefing and argument schedule that Avadel has proposed to Jazz, *see* Ex. B (Avadel Letter) at 1, and that Avadel will propose to the Federal Circuit. [redacted] All that entry of a stay would do is to permit Avadel to undertake clinical trial work and to share the results of that work with the FDA during the course of this appeal. That non-infringing conduct cannot harm Jazz. But, as explained

above, if the Court declines to stay the injunction and Avadel ultimately prevails on appeal, Avadel will be irreparably, and needlessly, harmed.

Jazz might argue that entry of a stay would abet the off-label use of LUMRYZ for IH, which would cause Jazz irreparable harm, but that argument fails for two reasons. First, this Court's injunction—which binds only Avadel—does not and cannot control off-label use because *Avadel* does not and cannot control off-label use. Avadel does not promote or market LUMRYZ for off-label uses, including IH. To the extent a doctor chooses to prescribe a medication off-label, that is a choice between the physician and patient and is not subject to this Court's injunction. Thus, whether the injunction is stayed has no bearing on whether doctors prescribe LUMRYZ for off-label use. [redacted] Such *de minimis* use cannot harm Jazz and does not outweigh the immediate and irreparable harm to Avadel that would come from disrupting its ongoing program to develop and submit information to FDA about LUMRYZ's efficacy and safety for IH patients.

Furthermore, any argument from Jazz that it would be harmed by a stay with respect to the treatment of pediatric narcolepsy similarly fails because the injunction does not bar Avadel from marketing LUMRYZ for pediatric narcolepsy. Indeed, the injunction expressly permits Avadel to "mak[e], us[e], and sell[ ]" LUMRYZ for "the treatment of narcolepsy." D.I. 666 at 2. While Jazz has taken the position that Avadel must *withdraw* its previously submitted application for approval to market to pediatric narcolepsy patients, *see* Ex. C (Jazz Letter) at 1-2, the injunction requires no such thing and Jazz never asked for any such relief with respect to pediatric narcolepsy patients, as discussed. Thus, whether the Court stays its injunction will no effect on Avadel's ability to market LUMRYZ for pediatric narcolepsy—it will instead remove Jazz's ability to improperly twist the injunction to threaten contempt.

D. The Public Interest Favors A Stay Pending Appeal

Finally, the public interest strongly favors a stay pending appeal. The scientific work of clinical trials is a public good that adds to the store of human knowledge—particularly where such trials identify safe and effective clinical treatments. Here, a stay of the Court's Order will enable Avadel to proceed with its ongoing clinical trial establishing the safety and efficacy of LUMRYZ for the treatment of patients suffering from IH. Avadel's clinical trial therefore serves the substantial public interest in the discovery of a safe—and potentially better—treatment for IH, should the injunction be lifted, or in the alternative, after the expiration of the '782 patent. In contrast, denying a stay would prevent Avadel from developing clinical study data establishing the safety and efficacy of LUMRYZ for treating IH. The detriment to the public interest goes beyond unnecessarily delay in IH patient access to LUMRYZ: if Avadel's ongoing study is disrupted, principal investigators responsible for enrolling IH patients in a new clinical trial will understandably question whether the best interests of their patients are served by enrolling them in a study that may be interrupted or end early. *See supra* at pp. 12-13; Gudeman Decl. at ¶¶ 6-9. Denial of a stay therefore threatens long-term consequences for the development of clinical safety and efficacy data that could establish the existence of an alternative—and potentially better—clinical treatment for IH patients. Such a result clearly runs afoul of the public interest.

Under Jazz's construction of the injunction, denial of a stay would also immediately harm IH patients currently enrolled in Avadel's clinical study. Jazz has demanded that Avadel cease enrolling new patients in the pending clinical trial and to terminate the open-label extension period for those who have already been enrolled and have been provided LUMRYZ as patients currently enrolled in its clinical trial, regardless of the benefit those patients may currently be receiving from LUMRYZ, and regardless of the consequences of rapidly switching between different treatments for their IH. *See* Ex. C (Jazz Letter) at 2. Further, the FDA routinely allows clinical trial

participants to receive a trial drug past the formal completion of the trial, both to gather additional safety data for submission to the FDA and to maintain continuity of patient treatment, a process known as an open label extension. *See* https://www.fda.gov/media/127712/download at 13 (encouraging study sponsors to make available an open-label extension study to ensure that all study participants will have access to the investigational treatment.); https://www.fda.gov/media/85675/download at 19 (noting that "[t]he goal of an open-label safety study is to better characterize the safety of a drug late in its development"). Under Jazz's construction of the injunction, denial of a stay would deprive clinical trial participants of the benefit of an open label extension, resulting in an abrupt end to those patients' access to LUMRYZ. *See* Ex. C (Jazz Letter) at 2 (seeking Avadel's confirmation that it would not "begin[] any open label extension of any ongoing study").

No public benefit attaches to these intrusions into the clinical-trial process. The public interest in this case favors a stay so that Avadel's clinical-trial work can proceed pending appeal.

IV. CONCLUSION

For the foregoing reasons, this Court should stay its Order granting a permanent injunction pending appeal of that injunction to the Federal Circuit.

Respectfully submitted,

Dated: September 3, 2024

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant	)	C.A. No. 21-691-GBW
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	)	C.A. No. 21-1138-GBW
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	)	C.A. No. 21-1594-GBW

- - - -

Wilmington, Delaware
Thursday, June 6, 2024
Permanent Injunction Transcript

- - - -

BEFORE: HONORABLE GREGORY B. WILLIAMS
UNITED STATES DISTRICT COURT JUDGE

- - - -

Michele L. Rolfe, RPR, CRR

62

sort of half awake and half asleep on Xywav. And actually in one instance when he was in college, the patient drove to a store and caused a disturbance in the middle of night not being aware that they were in this parasomnia state, and this is a really serious issue. This patient deserves access to Lumryz and deserves it every bit as much as the patients who were currently on it.

Now, although Jazz has tried to suggest that the injunctions that they seek are limited, we have put in evidence that even a limited injunction is, in effect, an injunction for everyone. Avadel is a one product company. Now, there's been a suggestion that's Avadel's own fault. I'm going to talk about that, but the point I want to make right now is whatever it is or isn't, it's not the patient's fault. I'm talking right now about public benefit. And from a public benefit point of view no patients will get this benefit if there is an injunction that precludes Avadel from being able to serve future patients.

THE COURT: Well, let me ask you --

MS. DURIE: Yes.

THE COURT: -- the same question I asked Mr. Cerrito: From a you public interest perspective, isn't there a difference between narcolepsy and IH?

MS. DURIE: I'm glad that the Court asked that because I was about to talk about IH. And the answer is

63

there is a difference, but there is a strong public benefit with respect to idiopathic hypersomnia too.

I think the most critical fact here is that although Jazz's counsel says that Xywav is approved for once-nightly, the evidence is that only about a quarter of patients with idiopathic hypersomnia are taking Xywav once-nightly and a quarter of it are taking twice-nightly, and the reason for that --

THE COURT: Even more basic than that because public interest is two factors, okay. You've got to public interest in protecting intellectual property, which, you know, encourages innovation; and then you've got the public interest in having access to the drugs. But one of the distinctions -- is there a distinction here between narcolepsy -- when it comes to access to the drugs, is there a distinction between narcolepsy, which is with respect to narcolepsy, there's been -- the FDA has said that Lumryz has some clinical superiority.

MS. DURIE: Correct.

THE COURT: But it hasn't done that with respect to IH.

MS. DURIE: Not yet. And the reason for the "not yet" is that Avadel has not yet done the clinical trial that would result in presenting that question to FDA.

THE COURT: Okay.

64

MS. DURIE: And one thing I want to note off the bat, Avadel is not engaging in any infringing conduct with respect to IH. Right now Avadel is selling Lumryz with a label for narcolepsy.

Your Honor referred to off-label usage. There is some, we don't promote it, we don't control it, we don't have anything to do with it, we're not allowed to. That is a judgment being made by an individual doctor about whether they're going to prescribe Lumryz for their IH patient. We don't do anything to encourage that.

And as the evidence shows, it's a very small number of patients. I think it's eleven patients, probably because there's no insurance coverage for it in that scenario.

Avadel has not yet started a clinical trial for idiopathic hypersomnia, it intends to. It intends to invest $35-40 million in that clinical trial. That clinical trial will fall within the FDA's safe harbor. That is infringing activity because we have made a policy judgment that we companies to conduct those clinical trials, regardless of issues with respect to patent infringement.

After that clinical trial has been done, Avadel will make a submission to FDA and FDA will then have an opportunity to evaluate whether Lumryz makes the same major contribution to patient care in idiopathic hypersomnia as it

65

does in narcolepsy.

Now, we have put in evidence as to why we think the answer to that question will be yes, and that is because we expect it to have the same benefit because most idiopathic hypersomnia patients take Xywav or Xyrem twice-nightly, and we think they will see the same benefits on Lumryz of being able to take a single dose and sleep through the night.

THE COURT: Okay. But infringement of Claims 14 and 24, its been said that Avadel doesn't currently do anything that infringes the patent. And one of the things that Jazz is asking for is a permanent injunction with regard to that. So if the Court granted the permanent injunction with respect to IH, that wouldn't put Jazz -- that wouldn't put Avadel out of business, right, because you aren't doing anything?

MS. DURIE: Well, I don't think that's necessarily correct. Avadel operates at a very substantial loss right now. It made huge investments in Lumryz well before it knew about Claim 24 of the patent or could have known. It made huge investments in clinical trials to bring a product to market with the hope that it would be able to recoup those expenses and then be able to continue to sell that product in a profitable way.

So actually Avadel does depend upon the ability

66

to grow and expand its business, that's part of the point of Mr. Divis' declaration, generally, in order to be able to continue to sell Lumryz. But I want to make sort of a fundamental point here: Yes, Jazz is asking for a permanent injunction. Nothing that Avadel will do would be subject to an injunction for a very long period of time, because Avadel can't infringe right now; it does haven't a FDA approval to sell a product and it won't have that FDA approval for years in the future. I think the estimate was something like three or four years, something on that order of magnitude. That is the first point of time at which there would even be a question about whether Avadel sales should be enjoined for idiopathic hypersomnia, because before then Avadel would not be infringing, it would be operating within this regulatory safe harbor that allows for conduct that would otherwise infringe if that conduct is intended to generate data for submission to FDA.

And, again, we have -- there's a reason that companies cannot infringe patents when they are conducting clinical trials that is because we want to encourage companies to do that. And we want to encourage companies to do that in order to generate the data that the Court would then be able to look at --

THE COURT: Right, but that's protected by statute --

67

MS. DURIE: That's protected by statute, that's exactly right.

At that point FDA will look at the data and make a decision about whether Lumryz offers a major contribution to patient care.

Now, again, Jazz bears the burden on this point. Jazz has put in, I will say, evidence about Xywav -- and I will talk about that -- but we have put in evidence from medical professionals explaining why there is a need now for patients with idiopathic hypersomnia for Lumryz and, therefore, why we expect that FDA is going to reach the same conclusion at the conclusion of those clinical trials.

So the first point most idiopathic hypersomnia patients take Xywav twice a night. On the label it says once a night or twice a night, most patients take it twice a night. So we put that in, that's evidence from Dr. Stern, that's in the declaration from Nurse Practice Maggie Lavender. This is not merely anecdotal evidence, although it is the only evidence from any medical professional on this. This is entirely unsurprising because this is what was reflected in the clinical trial for Xywav.

Now, on the Xywav label it says that in the clinical trial 23 percent of patients took Xywav once-nightly with a median dose of 4.5 grams and 77 percent of patients took it twice-nightly with a median dose of

68

7.5 grams. I want to explain how this clinical trial was structured because it's a little bit unusual.

Patients and their doctors were given the opportunity to identify to select the dosing regimen that they would be on, the one that as between these two Xywav options was credible or least bad for them. And as a result of those individualized decisions between doctors and patients, 77 percent of patients wound up taking Xywav twice-nightly. Then in the clinical trial aspect, half of those patients stayed on that drug at the dose and the dosing schedule that they had selected. The other half were switched to a placebo. And in the study what they evaluated was how much better patients did when they stayed on drug relative to what happened when they switched to a placebo.

But the thing that's critical about this is three-quarters -- more than three quarters of patents were taking it twice-nightly, which makes it entirely unsurprising the evidence we put in from doctors and from Nurse Practitioner Lavender is consistent with that.

So why is that if patients want to be able to sleep through the night? There are a number of reasons, but one of them has to do with dose. Xywav is an immediate release product. All of the drug that you take is immediately going to hit your system. For that reason, the maximum dose of Xywav that you can take at once is 6 grams,

69

because it isn't safe to have more than 6 grams hit your system at once. So if you are a patient who needs more than 6 grams of oxybate in order to get sleep, you're not going to get that with the once-nightly dose of Xywav.

Lumryz, by contrast, can be dosed up to 9 grams, and that's because you have that two-phase release, half of it releasing right away, half of it releasing later so it's safe for you to take a higher dose. And what we saw here on the Xywav label 77 percent of patients were taking Xywav twice-nightly median nightly dose of 7.5 grams, that's more drug, which presumably they and their physician determined that they needed than it would be possible for them to get if they were taking Xywav once-nightly.

THE COURT: Well, doesn't that also support the casual nexus because that's the invention of Claim 24, the immediate release and the modified release?

MS. DURIE: So both immediate release and modified release are elements of the claim, I agree with that. However, at trial, Jazz said with respect -- immediate release was in the prior art, everybody agrees with that.

At trial Jazz said "modified release was in the prior art." And it pointed to its earlier prior art disclosure of modified release in the '488 patent as providing the support for that for Claim 24.

74

23 percent of patient who is are on a once-nightly regimen. This is the actual data, and I want to note here this is from the Xywav approval package, Figure 5. And what it's showing here is the range of the sort of median and then the range of sort of outcomes from a statistical point of view for the once-nightly treatment and the twice-nightly treatment. The score that goes from zero to negative-11 is the Epworth sleepiness scale. And what is this is showing is how much better patients did or how much worse patients did when they went off drug or how much better they did when they stayed on drug, but the bigger the negative number the bigger the impact when they switched to placebo.

So a more negative number is the drug was more effective because there was a bigger effect, a bigger worsening of symptoms when they switched to a placebo. You see the numbers that are reported by Jazz about minus-3, which is a pretty big band for once-nightly, maybe minus-7.5 with a slightly smaller band, but still a significant one for twice-nightly. That's the data. This is something Jazz put in their reply brief. For that reason we don't have a declaration responding to it, but I would just note that that data looks pretty different in terms of the effectiveness of the once-nightly and the twice-nightly Xywav regimens for idiopathic hypersomnia.

The fundamental point here, Your Honor, with

75

respect to idiopathic hypersomnia is that Jazz has not met its burden, and it is its burden to show that these patients would not benefit and that there is, for that reason, a public benefit in precluding them from having access to this potentially life-changing treatment.

And in the *United Therapeutics* case the Court there found where at least some patients would likely suffer negative consequences that was a reason to conclude that the plaintiff has failed to do show that an injunction would be in the public interest. And I would suggest here we have put in a great deal of evidence about why we plan to invest money in a clinical trial and what we expect FDA's determination will be, why we expect they will reach the same conclusion, and essentially unrebutted evidence from medical practitioners about why it makes sense.

THE COURT: But isn't the difference here -- so you said yourself, as of today there's a very small number of patients that have -- that suffer from IH that have even been prescribed Lumryz.

MS. DURIE: That is true.

THE COURT: Right. And what was that number again?

MS. DURIE: I believe it's 11.

THE COURT: Eleven. All right. So in these cases where, you know, the differentiator of the product is

76

the basis to deny the permanent injunction the product has actually been prescribed, right?

MS. DURIE: No. And actually this *United Therapeutics* case is interesting because this was about whether defendant should be enjoined from launching the product for a particular medication. So there the product had not launched, and the Court said I'm not going to injoin the product from launching because I think doing so would mean that patients would likely suffer negative consequences if that product didn't launch.

The point here, Your Honor -- I mean, it's true Avadel has not yet done the clinical trial. Part of why Avadel didn't do the clinical trial yet was because of Jazz's conduct which kept it off the market as a function of the REMS patent and delayed the launch of Lumryz itself for narcolepsy. But be that as it may -- and I'll talk more about that, but be that as it may, the fundamental point idiopathic hypersomnia patients deserve access to the drug that is best for them just as narcolepsy patients do.

The timing of the clinical trials is not relevant to their need. So the only question should be have we -- has Jazz shown, has Jazz met its burden to show that the health of those patients will not be adversely impacted if the Court enters an injunction.

THE COURT: That's not the only question. The

77

question is does -- will the permanent injunction disserve the public interest. And, again, the public interest is two factors: The protection of intellectual property rights and then the accompanying healthcare benefits of patients. And so that's -- you know, the Court has to look at both of those factors and factor that in. And so that's sort of the state of -- sort of the use of the drug is different for narcolepsy as it is for IH.

MS. DURIE: Not in a way that I think is germane to the decision the Court needs to make. It is true in every case that there's a public interest in patent rights. What the Court's have said is we're not going to permanently injoin activities that would injure the public health, that the public health is sacrosanct. Again, where there is a differentiated impact that is a true public health impact.

So the timing and sort of what the status quo is, I don't think is relevant to that public health determination. The question is: Are those patients likely to receive the same benefit? And, again, I want to note there's nothing to injoin now. We're not doing anything in idiopathic hypersomnia to infringe. We need to run a clinical trial. There's nothing to injoin with respect to the clinical trial, that's not infringing.

At that point, FDA will look at the data and will make a decision. At that point, I suppose, maybe Jazz

with respect to whether or not an injunction, a permanent injunction is granted. The Court is going to decide the issue. I'm going to -- with respect to the ongoing royalty, that may be something that I defer until I get the post-trial motions because even Jazz says that, you know, it plans to file. I'm not saying that's what I'm going to do, but I'm going to think about that more. But I will rule on whether a permanent injunction should be granted or not, but I don't need a proposed findings of fact and conclusions of law.

MR. TIGAN: That's helpful, Your Honor. Those were due next week so that's good to know.

MR. CERRITO: Thank you, Your Honor.

THE COURT: All right. Well, thank both sides for your presentations. The Court will take the matter under advisement and issue a ruling.

Now there was -- I think Jazz had made a request to hear some additional motions on the antitrust and trade secret --

MR. CERRITO: We did, Your Honor.

THE COURT: But I denied that.

MR. CERRITO: You did. Yeah, you're just reminding us of the denial, Your Honor.

(Laughter.)

THE COURT: No. But once I rule on the

permanent injunction, I might look at it again to see whether it's something a hearing to be scheduled or argument on that, whether it makes sense or not. I don't have it in my head to understand whether -- you know, what the sort of connections are at this time, but it did occur to me that I might look at that after dealing with these issues.

MR. CERRITO: Understood, Your Honor.

THE COURT: All right.

(Whereupon, the following proceeding concluded at 12:47 p.m.)

I hereby certify the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

/s/ Michele L. Rolfe, RPR, CRR

U.S. District Court

EXHIBIT B

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LATHAM & WATKINS LLP

August 29, 2024

HIGHLY CONFIDENTIAL

Re: *Jazz Pharmaceuticals, Inc. et al v. Avadel CNS Pharmaceuticals, LLC*, C.A. Nos. 21-691, 21-1138, 21-1594 (GBW)

Counsel:

As you are aware, yesterday, Avadel filed its notice of appeal of the District Court's August 27, 2024 injunction order (the "Injunction Order"). After the Federal Circuit dockets the appeal, Avadel intends to seek expedited consideration of the appeal to ensure that it is resolved well in advance of activities that would be impacted by that injunction relating to FDA approval for a potential indication for LUMRYZ for the treatment of idiopathic hypersomnia ("IH"). Such activities would include Avadel seeking FDA approval (which, based on the current pace of the ongoing clinical trial, could start as soon as January 1, 2026) and conducting any new clinical trials (which would start before then).

To that end, Avadel proposes the following schedule for the appeal:

- Avadel's Opening Brief – Sept. 30, 2024
- Jazz's Responsive Brief – Oct. 28, 2024
- Avadel's Reply Brief – Nov. 12, 2024
- Appendix – Nov. 13, 2024
- Oral argument – first available argument calendar

Avadel believes this schedule gives both parties reasonable time to present their arguments. Please let us know Jazz's position on this expedited schedule.

In addition, as Jazz is certainly aware, on July 31, 2024, Avadel publicly announced that the first patient had been dosed in REVITALYZ, a Phase 3 clinical study evaluating LUMRYZ as a potential treatment for IH. *See* https://investors.avadel.com/news-releases/news-release-details/avadel-pharmaceuticals-announces-first-patient-dosed-phase-3. Avadel also announced that "[t]he study will enroll approximately 150 adults who are diagnosed with IH and includes an open label extension portion." *Id.* Avadel's view is that open label extensions are part and parcel of the ongoing IH trial and, therefore, patients who enroll in the ongoing IH trial may continue to

receive treatment pursuant to current or future open label extensions, consistent with the Injunction Order.

If Jazz takes a different view of the scope of the Injunction Order, please let us know within 48 hours. Under such a view, patients currently receiving treatment as part of the ongoing IH trial would be prohibited from continuing treatment during the open label extension period, which would begin as soon as early November, 2024 for the first-enrolled patients. As it is unacceptable to discontinue treatment of the REVITALYZ study participants during the open label extension period, Avadel would be forced to seek to expedite the appeal even more than the above schedule and/or to seek a stay pending appeal if Jazz believes that the Injunction Order prohibits the continued treatment of the REVITALYZ study participants pursuant to the open label extension.

Sincerely,

Kenneth G. Schuler
of LATHAM & WATKINS LLP

EXHIBIT C

REDACTED IN ENTIRETY

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that true and correct copies of the foregoing document were caused to be served on September 3, 2024 on the following counsel in the manner indicated below.

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Dated: September 3, 2024

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