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] **REDACTED – PUBLIC VERSION**
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	C.A. No. 21-1138 (GBW) [redacted] REDACTED – PUBLIC VERSION
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	C.A. No. 21-1594 (GBW) [redacted] **REDACTED – PUBLIC VERSION**

PLAINTIFFS' OPPOSITION TO DEFENDANT'S
EMERGENCY MOTION FOR STAY PENDING APPEAL

Confidential Version Filed: 9/10/24
Redacted Version Filed: 9/17/24

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Other Authorities

I. INTRODUCTION AND SUMMARY OF THE ARGUMENT

Avadel's attempt to stay the Court's limited injunction should be rejected. While Avadel's motion seeks to enjoin the Court's Order in its entirety, Avadel's briefing addresses only the REVITALYZ clinical trial for treatment of idiopathic hypersomnia (the "IH Trial") and an additional open-label extension study for IH after patients complete the IH Trial (the "OL Study"). But Avadel has not demonstrated any entitlement to a stay pending appeal for even portions of the injunction. On the merits, Avadel waived its safe harbor argument, introduced no evidence to support such an argument before this Court, and could not have carried its burden in any event. Nor can Avadel show any irreparable harm in the few months it will take the Federal Circuit to decide the appeal on the parties' agreed-upon expedited schedule. On the other hand, Jazz will suffer irreparable harm, as Avadel seeks to use a clinical trial and open label extension study to switch patients from Jazz to Avadel. The request for a stay should be rejected.[1]

First, Avadel is not likely to succeed on the merits of its appeal based on its safe harbor and First Amendment theories. As an initial matter, Avadel waived any purported safe harbor argument. Despite repeating the phrase "safe harbor" twenty-nine times in its opening brief, Avadel conspicuously avoids acknowledging that the safe harbor is an affirmative defense that Avadel never pled. In fact, even with full knowledge of the scope of the injunction Jazz sought, Avadel never argued that the safe harbor might apply until the June 4 injunction hearing. Proof of entitlement to the safe harbor defense requires fact and expert testimony and documentary evidence, none of which is in the record. The parties cannot present such evidence for the first time on appeal, so Avadel cannot prevail on the merits of this issue.

[1] There is no dispute regarding pediatric narcolepsy. Jazz confirmed it will not argue that Avadel's application for FDA approval of Lumryz for pediatric patients with narcolepsy, and Avadel's maintenance of that request, is in contempt of the injunction. Ex. 1 at 2; Ex. 2 at 1.

In any event, even if Avadel had pled the safe harbor defense, it could not have established the elements of that defense. For instance, Avadel does not even address whether—and could not have shown that—the infringing Lumryz dosage form that this Court's Order enjoins Avadel from making, selling, and using qualifies as a "patented invention" that falls within the safe harbor under §271(e)(1). Controlling Federal Circuit law holds that a "patented invention" subject to §271(e)(1) is one that cannot be used as a research tool immediately after patent expiration because the "patented invention," itself, still needs regulatory premarket approval. But Lumryz is already FDA-approved and, therefore, it does not fall under the statute's "patented invention" that is subject to the safe harbor under the facts present here.

Even assuming, *arguendo*, that the infringing dosage form is a "patented invention," Avadel also would have had the burden of demonstrating that its IH activities are "solely for uses reasonably related to the development and submission of information" to the FDA. 35 U.S.C. § 271(e)(1). Under Federal Circuit law, this means that Avadel would have had to demonstrate that its activities are required to obtain or maintain FDA approval for IH. Avadel did not present ***any*** evidence on this point. Nor would Avadel have been able to present the requisite evidence. For example, Avadel is seeking a pediatric narcolepsy indication without running ***any*** studies in pediatric narcolepsy and instead is relying on Jazz's pediatric narcolepsy studies.

Nor could Avadel have shown that the sole purpose of its IH activities was ***not*** a commercial purpose, as required to qualify for the safe harbor. Instead, the only record evidence shows that the true purpose of Avadel's proposed IH studies is to bolster enjoined off-label sales and usage in IH. Indeed, Avadel has already doubled its infringing sales in IH between the time of the June 4 injunction hearing and its opening brief here.

And, while Avadel attempts to immunize its infringement by characterizing the inunction

as an assault on the First Amendment, in reality Avadel seeks to permit conduct (IH trials) rather than speech. Neither the safe harbor nor the First Amendment protect this infringing conduct.

Second, Avadel fails to demonstrate both that it will suffer any irreparable harm and the lack of irreparable harm to Jazz. To start, any harm Avadel contends it will suffer related to the IH Trial is not imminent because Avadel admits it will not seek FDA approval for IH until [redacted] well after the appeal is decided. And Avadel's assertion that its reputation will be harmed from a delay in the clinical trial is both harm of its own making and lacking in factual support. Avadel put itself in its current position by initiating the IH Trial after it was found to be an adjudicated infringer, before this Court's injunction decision, and after it had told this Court it would ***not*** go forward with that trial if enjoined. At the same time, Avadel ignores the very real harm to Jazz caused by Avadel's flouting of the injunction Order and continued promotion and off-label sales of Lumryz for IH, [redacted][2]

Finally, Avadel's public interest argument likewise fails. Avadel's stay request merely rehashes arguments that this Court already considered and rejected in granting the injunction.

At bottom, Avadel's motion is a delay tactic aimed at giving it the ability to switch as many IH patients taking Jazz's Xywav product to Lumryz as it can before it complies with the injunction. Avadel told this Court at the June 4 hearing that the IH Trial had not started and that "if the Court were to decide . . . to injoin [sic] sales of IH . . . it's probably true that Avadel wouldn't run a

[2] Avadel admits that it is already selling Lumryz off-label for IH (Br. at 15), but wants its contempt of the injunction to be excused based on its declarant's testimony that "Avadel does not currently market or promote Lumryz for any off-label uses, including the treatment of idiopathic hypersomnia." Gudeman ¶ 11. But that fails to acknowledge that ***sales are also enjoined***. Since Avadel tracks (and quantifies) off-label usage, it undoubtedly can (and must) comply with the injunction and ensure that it does not make enjoined sales going forward. Should Avadel fail to do so, Jazz will promptly seek appropriate relief from the Court.

clinical trial." Ex. 3 at 85:22-86:8. Neither the IH Trial nor the OL Study were a "currently on-going clinical trial[]" under the injunction that Jazz sought. D.I. 586 at 6. Had Avadel just waited four weeks—as it said it would—it would not have placed patients and potential patients in the position that it did.

Indeed, Avadel's true aim is revealed in Avadel seeking to stay the injunction Order ***in its entirety***, even though it does not make any argument beyond the IH clinical trials and FDA submissions. Through this approach, Avadel seeks to lift the general prohibition against Avadel making, using, and selling Lumryz for IH and other non-narcolepsy indications, and also the reasonable royalty awarded to Jazz under the Order. Avadel's brief offers no purported basis for staying those portions of the Order. And if stayed, Avadel would continue increasing its currently-enjoined sales of Lumryz in IH. The Court should deny Avadel's motion.[3]

II. LEGAL STANDARD

Stays of injunctive relief are rarely granted because they are an "intrusion into the ordinary processes of administration and judicial review." *Nken v. Holder*, 556 U.S. 418, 427 (2009). As such, a party is not entitled to a stay of a permanent injunction as "a matter of right, even if irreparable injury might otherwise result." *Id.* at 433; *see* Fed. R. Civ. P. 62(c). The party seeking the stay "bears the burden of showing that the circumstances justify an exercise of [the Court's] discretion." *Nken*, 556 U.S. at 433-34. Courts balance four factors: "(1) whether the stay applicant has made a strong showing that [it] is likely to succeed on the merits [of its appeal]; (2) whether

[3] Given that the parties agreed to an expedited appeal regarding the injunction's scope, and this Court's recognition that the injunction's scope affects Avadel's antitrust action against Jazz (*see* C.A. No. 22-941, D.I. 94 at 2), Jazz respectfully submits that the antitrust case should be stayed pending resolution of the expedited appeal. The parties still have ***seventeen*** depositions left and then will embark on costly and time-consuming expert discovery (some of which may need to be ***repeated after the appeal***), all while briefing the expedited appeal. This all further supports Jazz's currently-pending motion to stay the antitrust case. *See* C.A. No. 22-941, D.I. 100 at 1-3.

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." *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990); *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 397 F. Supp. 2d 537, 548 (D. Del. 2005). The Court should consider whether the factors, when viewed as a whole, weigh against a stay of the permanent injunction. *Wonderland Switzerland Ag v. Evenflo Co., Inc.*, No. 20-727, 2023 WL 5569724, at *12 (D. Del. June 26, 2023).

III. ARGUMENT

A. Avadel Cannot Show A Likelihood Of Success On The Merits

Each of Avadel's arguments addressing this factor hinges on the safe harbor, an affirmative defense that Avadel never pled, let alone presented evidence on. In fact, Avadel only first raised the safe harbor at the June 4 injunction hearing, ***after*** briefing was closed. If pled or raised prior, and if Jazz would have had the opportunity to present evidence, it would have been readily apparent that Avadel would have been unable to carry its burden on the defense.

1. Any alleged safe harbor defense is waived

Avadel's belated grasp at a purported safe harbor defense is waived for two reasons.

First, "Section 271(e)(1) is an affirmative defense" that Avadel never pled. *See Regenxbio Inc. v. Sarepta Therapeutics, Inc.*, No. 20-1226, 2022 WL 609141, at *2 (D. Del. Jan. 4, 2022); *see also Galderma Labs., L.P. v. Medinter US, LLC*, No. 18-1892, 2020 WL 871507, at *2, n.2 (D. Del. Feb. 14, 2020) (same). "In responding to a pleading, a party ***must*** affirmatively state any avoidance or affirmative defense." Fed. R. Civ. P. 8(c) (emphasis added). "Failure to raise an affirmative defense by responsive pleading or by appropriate motion generally results in the waiver of that defense." *Charpentier v. Godsil*, 937 F.2d 859, 863 (3d Cir. 1991).

Specifically here, "the Safe Harbor Defense is an affirmative defense and is a separate and distinct defense from a non-infringement defense that Defendants must prove by a preponderance of the evidence. . . . Since it is an affirmative defense, Defendants must plead it in their answer . . . ." *Immunomedics, Inc. v. Roger Williams Med. Ctr.*, No. 15-4526, 2017 WL 58580, at *9 (D.N.J. Jan. 4, 2017) (citing *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 200 (2005) and *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014)). "[F]ailure to allege the Safe Harbor Defense is in and of itself a pleading deficiency." *Id.*

Despite Avadel first announcing possible IH trials in June 2023 (*see* PTX-0300.113), and despite Avadel's numerous Answers and Amended Answers, it ***never once*** pled the safe harbor defense. *See generally* C.A. No. 21-691, D.I. 11, 336; C.A. No. 21-1138, D.I. 12, 227; C.A. No. 21-1594, D.I. 24, 222. Nor is there any alleged safe harbor exception in Avadel's infringement stipulation for claim 24 of the '782 patent. *See* D.I. 550. Where "[a] review of Defendant['s] prior answers . . . shows Defendant[] ha[s] never asserted the Safe Harbor Defense . . . [,] Defendant[] ha[s] failed to meet the pleading standards." *Immunomedics*, 2017 WL 58580, at *9. For at least this reason alone, Avadel has waived any alleged safe harbor defense.

Second, if Avadel had pled it, Avadel would have been required to show entitlement to the safe harbor defense by a preponderance of the evidence. *Id.* Avadel neither presented this defense nor offered any evidence on it. The Federal Circuit will not consider the issue for the first time on appeal, so Avadel cannot prevail. The Court therefore need not grant the extraordinary relief Avadel seeks in its motion. Avadel argues it is likely to succeed in persuading the Federal Circuit that the safe harbor applies, but "[w]ith a few notable exceptions, such as some jurisdictional matters, appellate courts do not consider a party's new theories, lodged first on appeal. If a litigant seeks to show error in a trial court's overlooking an argument, it must first present that argument

to the trial court. In short, [the Federal Circuit] does not 'review' that which was not presented to the district court." *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1426 (Fed. Cir. 1997).

The safe harbor defense is a heavily fact-dependent inquiry, which makes Avadel's failure to present it even more problematic. *See, e.g., id.* (the Federal Circuit "declines to consider . . . novel infringement arguments" on appeal); *Natera, Inc. v. NeoGenomics Labs.*, 106 F.4th 1369, 1375 (Fed. Cir. 2024) ("Infringement is a question of fact."). The safe harbor inquiry has two prongs. Avadel failed to address either before this Court.

The first prong requires determining whether the infringing activity is with respect to a "patented invention" under the statute. Even to the extent the "patented invention" inquiry is a legal one, "every legal argument should be presented first to the trial court." *Rentrop v. Spectranetics Corp.*, 550 F.3d 1112, 1117 (Fed. Cir. 2008). Avadel never made any such presentation, and that alone supports the fact that Avadel waived and cannot succeed on appeal.

The second prong further solidifies Avadel's waiver. Prong two would have required Avadel to prove that its activities are "solely for uses reasonably related to the development and submission of information" to the FDA, which is highly fact intensive. For example, in *Amgen, Inc. v. Hospira, Inc.*, the Federal Circuit relied on expert and fact testimony and documentary evidence—***all of which had been presented to the trial court in the first instance***—to hold that "***[s]ubstantial evidence*** support[ed] the jury's finding" that infringing activity fell outside of the safe harbor because the infringing activity was not "'solely for uses reasonably related to the development and submission of information' to the FDA." 944 F.3d 1327, 1340 (Fed. Cir. 2019) (emphasis added). Avadel, having never raised the safe harbor defense or introduced any evidence on it before this Court, could not possibly carry its burden or succeed on appeal. *See id.* And, of

course, by waiting until the injunction hearing to first raise safe harbor, Avadel deprived Jazz the opportunity to develop the requisite factual record to enforce its patent rights.

On the record before this Court, it is clear that Avadel waived any purported safe harbor defense, and therefore cannot succeed on the merits of that defense on appeal. That waiver alone therefore warrants denial of the requested stay.

2. Avadel never addressed whether, nor could it have proven that, the infringing dosage form is a "patented invention" under §271(e)(1)

Any alleged safe harbor defense would also fail on the merits. Avadel is silent on whether its infringing Lumryz dosage form falls under the safe harbor's "patented invention" requirement. Under Federal Circuit law, if Avadel had pled the safe harbor defense, it would have been required to prove that its infringing Lumryz dosage form is "itself subject to the FDA premarket approval process," and not just being "used in the development of FDA regulatory submissions." *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008).

But here, none of Avadel's IH trials are aimed at obtaining or maintaining approval of the Lumryz dosage form, which Avadel would have to show qualifies as the "patented invention." Lumryz is already FDA-approved and, therefore, no longer subject to the FDA premarket approval process. And Avadel does not argue that the IH trials are necessary to maintain approval of the infringing Lumryz product. Instead, Avadel is using Lumryz as a research tool in the clinical trials in an attempt to increase its IH sales in the near term and, in the long term, allegedly to expand its labeling to include a second, new indication. "In short, [Avadel] is not a party seeking FDA approval for a ***product*** in order to enter the market to compete with patentee[]. Because the [infringing Lumryz dosage form] is not subject to FDA premarket approval, and therefore faces no regulatory barriers to market entry upon patent expiration," the safe harbor defense does not apply. *See Proveris*, 536 F.3d at 1265 (emphasis added).

While not addressing the "patented invention" inquiry, Avadel argues elsewhere in its brief that the injunction "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." Br. at 12-13. But this overlooks that the safe harbor provision was created because, if a patented product could not be used "for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval," 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." *Eli Lilly & Co. v. Medtronic, Inc*., 496 U.S. 661, 670 (1990) (emphasis added). But that is not what is happening here, because the Lumryz dosage form is no longer subject to premarket regulatory approval. Avadel can market Lumryz free and clear of the '782 patent the day the patent expires. There is no "extension of the patent term." Avadel's argument thus ignores that, "[f]ollowing *Proveris*, several district courts have held that where the patented ***product*** is not subject to FDA premarket approval, the safe harbor does not apply." *Regenxbio*, 2022 WL 609141, at *3 (collecting cases, emphasis added). And, in so doing, those courts have directly rejected Avadel's argument about an alleged patent term extension.

This District explained in *Regenxbio* that "[i]t may indeed be true that [the infringer] will be adversely affected by not being able to use Plaintiffs' patented [product], but the argument that this gives Plaintiffs an effective patent term extension makes no sense. [The infringer] is not using the patented [products] to obtain FDA approval to introduce generic [products] to compete in the marketplace when the [patent-in-suit] expires." *Id.* The same is true here. Lumryz is already FDA-approved and in the marketplace competing with Jazz's products; Avadel does not need to

obtain FDA approval of the infringing dosage form when Jazz's patent expires. Avadel, like the infringer in *Regenexbio*, "can begin using the patented [product in trials] immediately upon expiration of the patent because the [product is] not subject to any FDA regulatory approval process. Thus, [Jazz] will not receive any effective patent term extension." *See id.*

Indeed, the question is not whether Avadel can get approval of its IH indication the day the '782 patent expires. It is whether Avadel can use the infringing Lumryz dosage form the day the patent expires as a research tool in its IH studies. It unquestionably can and, therefore, Lumryz is analogous to the cultured cells that were at issue in *Regenxbio*. Thus, Avadel would not have been able to carry its burden on the "patented invention" prong. Indeed, Avadel did not even try. And Avadel should not be permitted to address this prong for the first time in reply because "[a]rguments raised for the first time before a district court in a reply brief are deemed forfeited." *Int'l Constr. Prods. v. Caterpillar Inc.*, No. 15-108, 2024 WL 406433, at *2 (D. Del. Feb. 2, 2024); *see also Mosaic Brands, Inc. v. Ridge Wallet LLC*, 55 F.4th 1354, 1362 n.7 (Fed. Cir. 2022) (same with respect to the Federal Circuit).

3. Avadel never presented any evidence on and could not have proven the "reasonably related" prong of §271(e)(1)

Avadel argues that the "reasonably related" prong "categorically protects clinical trials" and, therefore, that Avadel should be able to continue the IH Trial and any future IH-related clinical trials, including the OL Study. *See, e.g.*, Br. at 8-9. But Avadel overreaches, and the Federal Circuit has affirmed injunction language similar to that in the Order here. *See, e.g.*, *Natera*, 106 F.4th at 1374, 1381-83.

As a general matter, there is no "categorical[]" rule for the "reasonably related" prong. Instead, under Federal Circuit law (and assuming *arguendo* that Avadel could satisfy the "patented invention" prong), the proper "reasonably related" inquiry assesses whether each use of the

infringing Lumryz dosage form in each clinical trial is required to obtain or maintain FDA approval of an IH indication. *Amgen*, 944 F.3d at 1340. Avadel bears the burden of proving that any clinical trials are necessary for its desired IH indication under this prong. *Immunomedics*, 2017 WL 58580, at *9. Avadel, however, has not presented any evidence in support of its new argument and cannot do so for the first time on appeal. And, once again, Avadel could not have met its burden even if it had tried.

First, Avadel has not presented evidence that ***any*** clinical trial would be required to obtain approval for an IH indication. For example, Avadel applied for approval of a pediatric narcolepsy indication without doing ***any*** clinical trials in pediatric narcolepsy patients. Instead, the only pediatric narcolepsy studies that Avadel relied on were Jazz's Xyrem studies. *See* Ex. 4 at AVDL_01446735. Notably, the FDA found Avadel's application for pediatric narcolepsy to be "sufficiently complete" even though Avadel conducted no clinical trials of its own. *See* Exs. 4-5. Avadel has not presented any evidence that the FDA would fail to accept Avadel's application without a new trial (e.g., if Avadel relied on Jazz's studies with its other oxybate (Xywav) in IH in support of the use of Lumryz in IH). Avadel may dispute this, but the record is blank. Avadel did not present, and Jazz was not able to challenge, any evidence on this issue. The opportunity for Avadel to establish the need for the IH Trial, the OL Study, or any other trial in IH was before this Court. Avadel's failure to do so is not only a waiver for the reasons above, but also undermines its ability to succeed in arguing the same on the merits on appeal.

Second, even assuming that Avadel needed some IH trial for FDA approval, Avadel has not presented any evidence that it needs to enroll more patients in the IH Trial or conduct additional trials, including the OL Study, to obtain or maintain FDA approval. Jazz sought information on this exact question before Avadel initiated emergency motion practice, but Avadel refused to

provide it. *See* Exs. 2, 6-8. Even if some trial were necessary, which Avadel has not established, Avadel may not need to continue enrollment if the number of patients in the trial to date is sufficient. That would still leave open the question of the OL Study. But open-label extension studies are generally ***not*** required for FDA approval. Ex. 9 (stating the FDA's preference for blinded trials and recognizing the potential for bias in open-label trials). And Avadel cannot credibly claim that the OL Study is the same as the IH Trial. Instead, Avadel admits that open-label extensions "allow[] clinical trial participants to receive a trial drug past ***the formal completion*** of the trial." Br. at 16-17 (emphasis added).

Third, Avadel failed to present any evidence that the "sole purpose" of making and using each infringing Lumryz dosage form in those trials is ***not*** "to support its commercial sales efforts." *Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd.*, 96 F.4th 1347, 1355 (Fed. Cir. 2024). Even under the Federal Circuit's divided interpretation of the "solely" language in the "reasonably related" prong in *Edwards*, such "sole" commercial activity is excluded from the safe harbor defense. And literature has noted that open-label extensions "seem to be designed only to promote the use of the study drug and serve no valid research purpose." Ex. 10 at 573.

Moreover, Avadel has a history of: (1) [redacted] (D.I. 665 at 4); (2) publicizing clinical trial results before FDA approval for an indication (e.g., in publications, press releases, investor and scientific conferences, etc.) (*see* Exs. 11-13); and (3) widely publicizing its activities with respect to IH specifically, including communicating with prescribing doctors about the IH Trial (*see* Exs. 14-15; Gudeman ¶¶ 7-9). Had Avadel actually pled the safe harbor defense, Jazz would have offered evidence demonstrating that commercial activities are the sole purpose of Avadel's IH activities. Further, the purpose of Avadel's IH studies includes obtaining insurance coverage of Lumryz for IH

(without regard to FDA approval) and increasing sales of Lumryz for IH off-label. In fact, Avadel noted at the injunction hearing that its limited IH sales were "probably because there's no insurance coverage for it in that scenario." Ex. 3 at 64:5-14. Accordingly, Avadel would not have been able to demonstrate that the ***sole purpose*** of Avadel's IH activities would ***not*** be a commercial purpose. Thus, Avadel could not have met its burden.

4. Avadel's arguments regarding seeking FDA approval are baseless

Avadel argues that "the Patent Act provides that seeking FDA approval is not infringing activity." Br. at 8. But Avadel ignores that the Order does not enjoin seeking FDA approval in a vacuum. Instead, that relief is tied to Avadel's injunction on making, using, or selling the infringing Lumryz dosage form. *See* D.I. 666 at ¶ 1.

Avadel then argues that seeking FDA approval would be protected by the safe harbor and the First Amendment. Br. at 8-9. But Avadel's safe harbor argument fails for all of the same reasons set forth above. And, Avadel cannot explain why ***conduct*** that falls outside the scope of the safe harbor could be protected as petitioning the government. To be clear, because the parties have agreed that Jazz is not seeking to enforce the injunction against narcolepsy patients—including pediatric approval—Avadel's only argument related to petitioning the government is that it must be able to engage in clinical trials for IH to eventually seek FDA approval. For this reason, Avadel's First Amendment argument is a red herring. Unsurprisingly, none of Avadel's cited cases is a patent case, let alone one concerning an adjudicated infringer.

B. Avadel Has Not Shown That It Will Be Irreparably Harmed Absent A Stay

Nor has Avadel shown that it will be "irreparably injured" by the injunction pending appeal. *See Honeywell*, 397 F. Supp. 2d at 548; *Wonderland*, 2023 WL 5569724, at *2. Avadel incorrectly argues that, 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." Br. at 11. But Avadel has failed to demonstrate it will suffer any irreparable harm from complying with the injunction during the pendency of the appeal.

First, Avadel cannot show that any harm connected to "prohibiting Avadel from seeking an IH indication" is imminent. Avadel represented it would not apply for FDA approval for IH [redacted] and cannot market and sell the drug until 2036 at the earliest under the injunction. Given the expedited briefing schedule for appeal that will have the case ready for oral argument at the Federal Circuit by December 2024 or January 2025, *see* D.I. 677, any such "harm" will not occur before the appeal is decided. It therefore cannot provide the basis for a stay. For this same reason, Avadel's argument that "the injunction treads on Avadel's First Amendment right to petition the FDA—and that injury is irreparable per se," Br. at 14, fails. The appeal will be resolved well in advance of the projected [redacted] IH submission date and 2036 marketing date, rendering its irreparable harm claim speculative instead of imminent.

Second, Avadel cannot show irreparable harm based on its incorrect argument that its actions are "statutorily protected" by the safe harbor. Br. at 11-13. As explained, *supra*, Avadel waived any such defense and the safe harbor does not apply to Avadel's conduct in any event.

Third, Avadel's reputation arguments similarly fail because the claimed harm stems not from the injunction itself but from Avadel's decision to start and publicize the IH Trial after it had been adjudicated an infringer and after Jazz filed, and the parties argued, the injunction motion. Avadel created this situation by choosing to initiate the IH Trial at-risk. Had Avadel waited four weeks until the August 27 injunction decision, instead of starting the IH Trial at the end of July, it would have known what it was permitted, or not permitted, to do. Avadel cannot prevail on a theory "that successful exploitation of infringing technology shields a party from injunctive relief."

Broadcom Corp. v. Qualcomm Inc., 543 F.3d 683, 704 (Fed. Cir. 2008).

For this same reason, the Court should reject Avadel's argument that it will suffer irreparable harm pending appeal because marketing Lumryz for IH is one of "its core business objectives" and delaying an IH indication harms Avadel's "reputation." Br. at 12. Any such harm would not stem from the injunction itself but rather from Avadel's decision to start the IH Trial at-risk. Avadel has not argued, and certainly not established with any evidence, that it was ***required*** to initiate the IH Trial when it did. Thus, to be clear, any complaint Avadel now makes about the impact of disrupting that trial, is the result not of the Court's decision to grant the injunction, but of Avadel's own conduct. Avadel earned the "reputation" of an adjudicated infringer that continues to use the infringing Lumryz dosage form. Thus, Avadel cannot claim that reputational harm stems from the injunction—as opposed to its continued infringement. Avadel cites no case law to support the contention that being enjoined from infringement constitutes irreparable harm simply because the infringing company considers its enjoined activity to be a "core business objective."[4] Avadel's choice to initiate a new infringing activity after the verdict cannot be the basis to relieve Avadel from consequences for infringing.

Finally, unlike Jazz's motion for a permanent injunction and the extensive briefing surrounding it (D.I. 587 at 3-11; D.I. 610 at 3-4), Avadel has not offered meaningful evidence to demonstrate any "irreparable harm." While Avadel contends that any delay in the IH Trial "can damage the confidence of physicians" and may make "recruitment more difficult," *id.* (citing Gudeman ¶¶ 9-11), such arguments are speculative at best. Avadel offers no proof that such harm is imminent or irreparable with respect to the IH Trial specifically, and instead offers only a general

[4] Avadel cites no authority for the extreme position that the stay should be granted because Avadel, an admitted infringer, is concerned about its reputation in working to undo the impact of its infringement and calculated decision to initiate the IH Trial pending the injunction decision.

conclusory declaration from Jennifer Gudeman, who is not a physician. Such conclusory assertions cannot establish irreparable harm. *Sunoco Partners Mktg. & Terminals L.P. v. Powder Springs Logistics, LLC*, No. 17-1390, 2018 WL 395750, at *14 (D. Del. Jan. 8, 2018) (finding that "conclusory and speculative allegations" are insufficient to "demonstrate irreparable harm."). Also, as noted above, open-label extension studies are generally not required for FDA approval (Ex. 9), and it has been recognized that, in many cases, open-label studies are merely "[d]ressing up marketing exercises as research" (Ex. 10 at 573). Rather than avoiding purported irreparable harm, Avadel's insistence on being allowed to conduct the OL Study is motivated by a desire to end run around the injunction to promote Lumryz for IH.

Indeed, in attempting to compromise and obviate the need for the Court to decide this motion, Jazz repeatedly asked Avadel straightforward questions regarding (a) how many patients are currently enrolled in the IH Trial; (b) how many of those patients are currently on drug (as opposed to placebo); and (c) the number of patients on drug that would be subject to the OL Study from November 2024 through January 2025. Ex. 6. Avadel would only state that the patients in the IH Trial "fluctuate day to day as new patients join the study and others leave the study," and that "some enrollees" will be eligible for the OL Study in November 2024. Ex. 7. When Jazz reiterated its request (Ex. 2), Avadel unilaterally declared that the parties were at an "impasse" (Ex. 8). That Avadel refused to provide even this basic information to Jazz makes apparent that Avadel's true aim is not to even allegedly maintain the status quo pending appeal, but rather to have free-range to switch IH patients from Jazz's Xywav product to Lumryz and to do so in successive and unnecessary clinical trials and open-label extensions.

At bottom, Avadel does not dispute that it stands to make billions on sales of Lumryz to treat narcolepsy, which are carved out of the injunction. *See* D.I. 587 at 18-19; D.I. 610 at 5.

Accordingly, there is no basis for finding irreparable harm to Avadel in the absence of a stay given the substantial amount Avadel stands to earn in non-enjoined activity. *See, e.g.*, *Honeywell Int'l*, 397 F. Supp. 2d at 550 (finding "[defendant] will not be irreparably injured absent a stay because, as was discussed above, [defendant] is a solvent entity capable of surviving" the injunction); *ePlus Inc. v. Lawson Software, Inc.*, 946 F. Supp. 2d 503, 510 (E.D. Va. 2013) (defendant's "size and financial strength" weighed against "irreparable injury").

C. Staying The Injunction Would Cause Substantial Harm To Jazz

Staying the injunction will cause the same substantial harm to Jazz that the Court determined Jazz would suffer absent an injunction. Whether the stay "will substantially injure" Jazz must be considered. *Honeywell Int'l*, 397 F. Supp. 2d at 548; *Wonderland*, 2023 WL 5569724, at *2. Avadel glosses over the irreparable harm that its infringement has caused, and is causing, Jazz. And it fails to take into account that Avadel's requested stay is rooted in Avadel's calculated decision to initiate the IH Trial while the Court's injunction decision was pending.

In granting the injunction, the Court recognized that: Xywav is the only FDA-approved treatment for IH; that, if approved by the FDA for IH, Lumryz would compete head-to-head against Xywav in a newly-developing market; that Avadel was targeting the IH market because of Jazz's nascent market penetration; and that "an encroachment by Avadel at such a 'crucial inflection point' in the development of the IH market would harm Jazz by allowing Avadel to 'capture and define the market with pirated technology.' D.I. 665 at 22-23 (internal cites and quotes omitted). Despite being found to irreparably harm Jazz with respect to IH, Avadel seeks to blithely continue its infringement unabated by, among other things, promoting Lumryz to doctors to treat IH (*see* Gudeman ¶¶ 7-9), and conducting the OL Study. Br. at 13. All of Avadel's IH activities are being done to promote Lumryz for an infringing use in IH. Further, despite having been found to infringe Jazz's valid '782 patent, Avadel last month claimed that "people living with IH have been severely

constrained in a lack of approved treatment," despite Xywav being approved once-nightly to treat IH. Ex. 15 at 5. Avadel further told investors that Lumryz will present a "a higher therapeutic option" than Xywav in IH, despite there being absolutely no scientific evidence of such. *Id.* at 19. Instead, as this Court recognized, the "clinical research f[ound] no substantial difference between once nightly dosing and twice nightly dosing of Xywav for IH treatment." D.I. 665 at 27.

Avadel cites no case law to support a stay that would in large part nullify the Court's injunction Order. Indeed, a stay is a rare "intrusion" into the ordinary judicial process. *Nken*, 556 U.S. at 427. This is all the more true for a stay that would in many respects render the Court's IH permanent injunction a dead letter. *See Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011) (the "fundamental nature of patents as property rights [is] granting the owner the right to exclude" (citing U.S. Const. art. I, § 8, cl. 8)).

Further, as the Court recognized, Avadel engaged in "[redacted] D.I. 665 at 4. If the IH Trial is permitted, and Avadel generates and publicizes data for Lumryz in IH, [redacted] Decl. of P.J. Honerkamp at ¶¶ 11-13. [redacted] *See id.* This would further cause irreparable harm to Jazz. *See* D.I. 665 at 4.

Avadel asserts that Jazz will not be irreparably harmed because the expedited appeal will likely be resolved before Avadel receives FDA approval for the IH indication. *See* Br. at 14. This same schedule undercuts the purported harm to Avadel absent a stay. Moreover, Avadel ignores its ongoing efforts to promote Lumryz for IH at the expense of Jazz's marketing of Xywav for IH. Further, concerning Avadel's downplaying of admitted off-label use of Lumryz to treat IH (Br. at

15), Avadel has refused Jazz's request that Avadel keep Jazz apprised of such off-label use (*see* Br. Ex. C at 2). There is therefore no way for Jazz to monitor or corroborate such infringing use that is likely the result of Avadel's public statements touting the alleged benefits of Lumryz to treat IH, despite having no evidence to support its claims. Avadel has not shown, and cannot show, that staying entry of the injunction will not substantially injure Jazz.

D. The Court Has Already Determined Public Interest Weighs In Jazz's Favor

Finally, Avadel's public-interest arguments simply rehash its opposition to Jazz's motion for a permanent injunction. *See* Br. at 16-17; D.I. 601 at 9-10. The Court considered, and rejected, these arguments. D.I. 665 at 25-29. In so doing, it issued a narrow injunction, exempting Avadel's sale of Lumryz to treat narcolepsy patients. *Id.* at 21. However, the Court recognized the differences in the public interest for narcolepsy and IH, and found that the public interest weighed in favor of Jazz for IH because IH is a separate condition from narcolepsy, and Jazz's Xywav has been FDA-approved for once-nightly treatment of IH. *Id.* at 27-28.

Avadel now argues that the injunction allegedly harms the "public interest in the discovery of a safe—and potentially better—treatment for IH." Br. at 16. But the Court fully considered that alleged interest and found that, based on the parties' evidence, "Avadel failed to show that Lumryz is a superior or unique treatment for IH." D.I. 665 at 29. Avadel does not address the Court's public interest findings, which are more than sufficient to demonstrate that the public interest is not harmed by the injunction, and certainly does not weigh in favor a stay.

Avadel also ignores the Court's finding that for IH, the "public's interest in enforcing patent rights and encouraging innovation" outweighs any hypothetical, unsupported benefit claimed by Avadel. *Id.* The Court's statement of the law is well supported. The Federal Circuit has repeatedly held that there is a strong public policy in enforcing valid patent rights against infringing products. *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 931 (Fed. Cir. 2012)

(stating that "investment in drug research and development must be encouraged and protected by the exclusionary rights conveyed in valid patents" and "[t]hat incentive would be adversely affected by taking market benefits away from the patentee and giving them to the accused infringer in this case"); *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1567 (Fed. Cir. 1996) (noting "the strong public policy favoring the enforcement of patent rights"). And the Court rejected the argument Avadel repeats here (*see* Br. at 11) that Avadel should be permitted to conduct clinical trials and delay the injunction pending the results and any alleged comparison of Lumryz to Xywav. *See* Ex. 3 at 78:15-25 ("But if a competitor can, at any time, just come in to court and say well, you know, we're going -- we are coming up with a competitive drug that infringes Company A's patent, but our drug is going to have some differentiating feature that is going to more benefit patients, if that -- and it doesn't matter whether that drug was in the market being currently prescribed and would be being taken away from patients as opposed to a drug that's been in the market, has been prescribed to patients, you know, if you don't put some limit on it at some point then that's just opening the door for infringement.").

Given that Avadel's public interest arguments are largely the same as those that the Court previously considered when ruling on Jazz's motion for a permanent injunction, they should carry little weight. *See Tristrata Tech., Inc. v. ICN Pharms., Inc.*, No. 01-150, 2004 WL 856595, at *3 (D. Del. April 12, 2004) (rejecting a stay where the public interest arguments "are merely repetitions of arguments previously rejected by the Court.") Accordingly, the public interest will be served by enforcement of the injunction and the denial of Avadel's request for a stay.

IV. CONCLUSION

For the foregoing reasons, Jazz respectfully requests the Court deny Avadel's motion.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

Attorneys for Plaintiffs
Jazz Pharmaceuticals, Inc. and
Jazz Pharmaceuticals Ireland Limited

OF COUNSEL:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Andrew S. Chalson
Gabriel P. Brier
Frank C. Calvosa
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

September 10, 2024

CERTIFICATE OF SERVICE

I hereby certify that on September 10, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 10, 2024, upon the following in the manner indicated:

Daniel M. Silver, Esquire — *VIA ELECTRONIC MAIL*
Alexandra M. Joyce, Esquire
McCarter & English, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
Attorneys for Defendant

Kenneth G. Schuler, Esquire — *VIA ELECTRONIC MAIL*
Marc N. Zubick, Esquire
Alex Grabowski, Esquire
Sarah W. Wang, Esquire
Michelle Chin, Esquire
Latham & Watkins LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
Attorneys for Defendant

Herman H. Yue, Esquire — *VIA ELECTRONIC MAIL*
Franco Benyamin, Esquire
Ramya Sri Vallabhaneni, Esquire
Latham & Watkins LLP
1271 Avenue of the Americas
New York, NY 10020
Attorneys for Defendant

Alan J. Devlin, Esquire — *VIA ELECTRONIC MAIL*
Ian Conner, Esquire
Denise Laspina, Esquire
Kelly Welsh, Esquire
Latham & Watkins LLP
555 Eleventh Street, NW, Suite 1000
Washington, D.C. 20004-1304
Attorneys for Defendant

Daralyn J. Durie, Esquire *VIA ELECTRONIC MAIL*
Rebecca E. Weires, Esquire
Adam R. Brausa, Esquire
Tannyr Pasvantis, Esquire
Umeet K. Sajjan, Esquire
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105
Attorneys for Defendant

Kira A. Davis, Esquire *VIA ELECTRONIC MAIL*
Henry Huttinger, Esquire
Katherine E. McNutt, Esquire
Rose S. Lee, Esquire
MORRISON & FOERSTER LLP
707 Wilshire Boulevard
Los Angeles, CA 90017
Attorneys for Defendant

David F. McGowan, Esquire *VIA ELECTRONIC MAIL*
David F. Kowalski, Esquire
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, CA 92130
Attorneys for Defendant

Andrew T. Jones, Esquire *VIA ELECTRONIC MAIL*
MORRISON & FOERSTER LLP
2100 L Street, NW, Suite 900
Washington, D.C. 20037
Attorneys for Defendant

Scott F. Llewellyn, Esquire *VIA ELECTRONIC MAIL*
MORRISON & FOERSTER LLP
4200 Republic Plaza
370 Seventeenth Street
Denver, CO 80202-5638
Attorneys for Defendant

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239