IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	REDACTED PUBLIC VERSION FILED AUGUST 12, 2025 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]

AVADEL'S ANSWERING BRIEF IN OPPOSITION TO
PLAINTIFFS' RENEWED MOTION FOR A PERMANENT INJUNCTION

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INTRODUCTION

The Federal Circuit rejected the injunction Jazz sought post-trial, emphasizing that "[a]n injunction is a 'drastic and extraordinary remedy,'" and that while permanent injunctions are possible in appropriate circumstances, "this is not such a case." *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 136 F.4th 1075, 1082 (Fed. Cir. 2025) (citation omitted). Jazz's renewed motion seeking to enjoin Avadel from submitting a supplemental New Drug Application ("sNDA") for LURMYZ for the treatment of idiopathic hypersomnia ("IH") again invites error. Jazz ignores the Federal Circuit's opinion in multiple respects and pretends that the Federal Circuit rejected Avadel's arguments on the *eBay* factors. Not so. The Federal Circuit specifically instructed that if Jazz again seeks to enjoin such activity on remand, "the district court must address the *eBay* factors anew in accordance with this opinion before again enjoining that activity." *Id.* at 1089. Yet Jazz fails even to mention changed facts relevant to that assessment—facts that confirm that there is no necessity for the drastic injunction Jazz seeks. Properly assessed, the *eBay* factors uniformly warrant rejecting Jazz's proposed injunction. As the Federal Circuit observed, there is no guarantee Avadel's clinical study will succeed or that Avadel will even submit its sNDA, let alone that FDA will approve it. So any potential harm to Jazz is speculative and tenuous.

Conversely, the harm to both Avadel and the public from Jazz's injunction would be concrete and immediate. Last month, LUMRYZ was awarded Orphan Drug Designation ("ODD") for the treatment of IH on the plausible basis that its once-nightly dosing will provide a major contribution to patient care—the same grounds that FDA recognized in granting Orphan Drug Exclusivity ("ODE") to LUMRYZ for narcolepsy and that this Court recognized as a "crucial" factor in not enjoining LUMRYZ sales for narcolepsy. But ODE is only awarded with final FDA approval. Jazz moves to enjoin Avadel from *even seeking approval* for IH in order to prevent FDA from making that same finding and awarding LUMRYZ ODE for IH, and giving the Court a full

record to consider. For this reason, the balance of harms and the public interest overwhelmingly favor allowing FDA to finalize its assessment by permitting Avadel to submit an sNDA for IH. Further, Jazz ignores the harm from restraining Avadel's core First Amendment right to petition the government—activity that Congress expressly sought to protect. Indeed, Jazz makes no attempt to satisfy its burden to justify such an impingement on Avadel's constitutional rights.

Finally, Jazz ignores the actions Avadel has taken and will continue to take to stop sales of LUMRYZ for non-narcolepsy indications so long as the Court's injunction remains in effect. These measures have been effective, and more drastic measures are not necessary, particularly because of the harm they would cause the public.

LEGAL STANDARDS

An injunction is a "drastic and extraordinary remedy." *Jazz*, 136 F.4th at 1082 (quoting *Apple Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1359 (Fed. Cir. 2013)). For a permanent injunction, Jazz has the burden to show "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006).

In that analysis, Jazz must demonstrate "a sufficiently strong causal nexus" tying its alleged irreparable harm "to the … infringement." *Jazz*, 136 F.4th at 1089 (quoting *Apple*, 735 F.3d at 1359-60). And, crucially, because Jazz seeks to enjoin now-concededly non-infringing conduct (submission of an sNDA to FDA), it must show that such an injunction is "***necessary*** to prevent infringement"; a "speculative and tenuous" claim of infringement is not enough. *Id.* (emphasis added) (citing *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1367 (Fed. Cir. 1998)). Thus, the requisite strong causal nexus is absent where there is a "long lead time before" the alleged

future infringement and where "new development[s]" might occur "in the interim." *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 776-77 (Fed. Cir. 1993); *Jazz*, 136 F.4th at 1088-89. And in evaluating necessity, the Court should look to "an alternative to prohibiting otherwise lawful [] activity," including steps by a defendant "to preclude direct infringement." *Joy*, 6 F.3d at 777. Moreover, if Jazz "fails to show 'that the public interest would not be disserved by a permanent injunction,' then [this Court] may not issue an injunction." *Amgen, Inc. v. Sanofi*, 872 F.3d 1367, 1381 (Fed. Cir. 2017) (citation omitted).

ARGUMENT

I. As Jazz Concedes, Filing For FDA Approval Is Non-Infringing Activity

The Federal Circuit instructed the parties to brief and the Court to consider "whether Avadel's submission of a [LUMRYZ sNDA] for an additional indication … would be an act of infringement under 35 U.S.C. § 271(e)(2)" if the issue remains contested. *Jazz*, 136 F.4th at 1089. Jazz ignores that question and implicitly admits that such a submission "do[es] not … constitute infringement." D.I. 747 at 4. Rightly so, an Avadel sNDA would not implicate any Orange Book-listed patents. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *Eisai v. Mutual Pharm.*, No. 06-3613, 2007 WL 4556958, at *12 (E.D. Tex. Dec. 20, 2007); H.R. Rep. 98-857 pt. 1 at 46 (1984). Thus, any potential LUMRYZ sNDA filing by Avadel will be non-infringing activity, and any future argument by Jazz to the contrary is waived.

II. The Federal Circuit Did Not Reject Avadel's *eBay* Arguments

Before addressing its substantive arguments, Jazz asserts (at 2, 4) that the Federal Circuit rejected Avadel's *eBay* factors arguments. That is incorrect. To the contrary, the Federal Circuit found that the Court's analysis improperly focused on LUMRYZ's *entrance into the market* for IH. *Jazz*, 136 F.4th at 1089. As the Federal Circuit concluded, this "analysis is insufficient to support" enjoining Avadel from requesting FDA approval for IH. *Id.* at 1088-89. Because Jazz

did not argue that Avadel's submission of an sNDA for IH is an act of infringement under 35 U.S.C. § 271(e)(2), *see supra* at § I, the remedy ordered by the Federal Circuit is for the Court to "*address the* eBay *factors anew* in accordance with [the Federal Circuit's] opinion." *Id*. at 1089 (emphasis added). Simply put, Jazz is wrong, and finding otherwise is plain error.

III. The *eBay* Factors Do Not Support Jazz's Broad Injunction Request

A. Approval of LUMRYZ For IH Would Not Cause Jazz Irreparable Harm

1. Jazz's Assertions of Future Infringement Are Insufficient

Jazz again argues that if LUMRYZ is approved for IH, Jazz will be irreparably harmed by lost market share, price erosion, and reputational harm. The Federal Circuit found otherwise:

> It well may be that Jazz would be irreparably harmed upon Lumryz's entrance into the IH market. But entitlement to an injunction requires a showing that there is a "causal nexus" between the alleged irreparable harm and the *enjoined activity*. *See Apple Inc.*, 735 F.3d at 1359–60 . . . . Here, the only findings to support enjoining Avadel from seeking FDA approval relate to the harm Jazz would suffer if Avadel were to enter the market for the IH indication—not if Avadel were merely to apply for FDA approval of that indication.

Jazz, 136 F.4th at 1089. While Jazz asserts that enjoining Avadel from filing an sNDA is necessary to prevent future infringement, the Federal Circuit emphasized that the required nexus is absent where the alleged future infringement is contingent on future events. *Id.*; *supra* at 2-3. Thus, an injunction is unnecessary to prevent future infringement where there was a "very long lead time before use can begin," where "new development[s]" might occur "in the interim," and where it was in the seller's "interest to take steps to preclude direct infringement." *Joy*, 6 F.3d at 776-77.

That reasoning applies here. "Although Avadel's ability to enter the market is, in part, dependent on Avadel seeking FDA approval, it does not follow that enjoining Avadel's sNDA would be *necessary* to prevent infringement" because "any number of things may prevent that approval from ever arriving." *Jazz*, 136 F.4th at 1089. Jazz presumes that the sNDA process will necessarily lead to IH sales. That is wrong and contrary to the Federal Circuit's decision for

multiple reasons: (1) Avadel's clinical trial may not succeed; (2) applying for an IH indication for LUMRYZ does not necessarily mean that FDA will grant that application; and (3) Jazz fails to prove there will be irreparable harm specifically caused by the *approval* for an IH indication. The Federal Circuit highlighted these precise uncertainties:

> Future infringement, *e.g.*, commercialization of Lumryz for IH, can only occur if and when the FDA approves Lumryz for that indication. And any number of things may prevent that approval from ever arriving. Avadel may decide the financial investment in pursuing the approval does not comport with its business prospects. Clinical trials may fail. The district court's analysis is simply too speculative and tenuous to reasonably conclude from its findings that enjoining Avadel from applying for FDA approval is necessary to prevent future infringement.

Id. at 1089. The Federal Circuit's observations remain true—neither Avadel's clinical study nor a possible sNDA filing will necessarily lead to infringement. Enjoining Avadel from filing an sNDA is simply not "necessary to prevent infringement," and Jazz fails to show the strong causal nexus for this reason alone. *See Johns Hopkins*, 152 F.3d at 1365-67 ("Judicial restraint of lawful noninfringing activities must be avoided."); *TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869, 890 n.9 (Fed Cir. 2011) (Federal Circuit has "strongly discouraged judicial restraint of noninfringing activities").

Jazz's efforts to overcome this lack of causal nexus do not withstand scrutiny. The selected excerpts from Avadel press releases and earnings transcripts that Jazz relies on do not negate the uncertainties inherent to whether Avadel's sNDA will ever actually result in harm to Jazz. To the contrary, they reinforce those uncertainties.

First, while Avadel is currently running a clinical study on IH that is on track to complete enrollment by the end of 2025, neither that date nor the success of the clinical trial is assured. Gudeman Decl. at ¶ 8. Avadel said as much—*explicitly*—in the very document Jazz relies upon, noting that the actual enrollment and timing of the clinical study may "differ materially" from

Avadel's current expectations. *See* D.I. 747-1 Jazz Ex. 1 at 7-8 (identifying Avadel's "idiopathic hypersomnia clinical study for LUMRYZ, including enrollment and timing related thereto" as a "forward-looking statement[]" that is "subject to significant risks"). The same is true of Jazz's citations to various Avadel earnings calls. *See* D.I. 747-1 Jazz Ex. 2 at 2 (identifying several matters as "forward-looking statements" that are "subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements"); Ex. 3 at 2 (same); Ex. 4 at 2 (same); Ex. 5 at 2 (same); Ex. 6 at 2:12-22 (same); Ex. 8 at 2-3 (same). In short, no one can guarantee the outcome of a clinical trial—it wholly depends on the data derived from the trial. Gudeman Decl. at ¶ 9. Thus, while Avadel has reasonable confidence in LUMRYZ and its potential to treat IH, Jazz is wrong that the result is a *fait accompli*.

Second, even if Avadel's clinical trial is successful and Avadel files its sNDA, there is no certainty as to when Avadel will make that filing. Gudeman Decl. at ¶ 10. Moreover, there is no certainty that FDA will approve that application. *Id.* at ¶ 11. These uncertainties belie Jazz's assertion that enjoining the filing of an sNDA is necessary to address infringement.

Third, even if Avadel files an otherwise-approvable sNDA, Jazz's Xywav product still has ODE for IH, meaning that Avadel could only overcome that block by demonstrating that LUMRYZ is clinically superior to Xywav. 21 U.S.C. § 360cc(c); 21 C.F.R. § 316.3(b)(3), (14). If Avadel does not overcome that ODE, LUMRYZ will not get approved for IH and Jazz will not suffer any harm. 21 C.F.R § 316.31. Stated differently, there are only two possible outcomes of Avadel submitting its sNDA. First, FDA could decline to approve the sNDA, in which case there would be no harm to Jazz. Alternatively, FDA could find that LUMRYZ is clinically superior to Xywav *for IH*, such that there is no ODE block and FDA can approve the sNDA. That is what happened with narcolepsy. If that is what happens in IH, Avadel would ask the Court to revisit its

injunction decision and come to the same conclusion with respect to IH that it did with narcolepsy, so as to not deprive patients of a clinically-superior treatment. Thus, in any situation where Avadel's sNDA is actually approved, the public interest would outweigh any alleged harm to Jazz.

Given the foregoing, Jazz's claim of future infringement remains "speculative and tenuous," and its requested injunction is improper. *Jazz*, 136 F.4th at 1089; *Joy*, 6 F.3d at 776-77.

2. Jazz Fails to Account for Avadel's Protective Measures

In evaluating necessity, the Court should look to "an alternative to prohibiting otherwise lawful [] activity," including steps by a defendant "to preclude direct infringement." *Joy*, 6 F.3d at 777; *see also Veracode, Inc. v. Appthority, Inc.*, 137 F. Supp. 3d 17, 97 (D. Mass. 2015) (finding that "prohibiting the manufacture, use, or sale of the Platform *as a whole* [is] unnecessary" where the Defendant presented evidence that it could "reasonably segregate" the infringing activity). Take the court's opinion in *Brooktrout, Inc. v. Eicon Networks Corp.*, No. 03-59, 2005 WL 8160605 (E.D. Tex. July 25, 2005) (cited at D.I. 747 at 5, 11). There, the jury found that customers infringed the patents-in-suit by using defendant's product in accordance with the instructions provided therewith. *Id.* at *2. The patentee sought to enjoin all sales of the product. *Id.* at *4. The court rejected this proposal as going "beyond [what] is necessary to deter future unlawful conduct." *Id.* at *6. The court explained that meaningful relief must be considered against the extent to which "the scope of the requested relief will impair lawful activity." *Id.* Because the proposed injunction would have "a significant impact on lawful activity," the court instead ordered defendant to publish warnings on manuals distributed with its products and refrain from posting instructions on how to operate the product in an infringing manner. *Id.* The court reasoned these narrower "restrictions [we]re sufficient to guard against the threat of future unlawful conduct." *Id.*

Judge Jordan's decision in *C.R. Bard, Inc. v. U.S. Surgical Corp.* is similarly instructive. 258 F. Supp. 2d 355 (D. Del. 2003). There, the patentee sought to enjoin sales of defendant's

product even though only one method of using the product infringed. *Id*. at 362. The patentee insisted that "anything short of a complete ban on the domestic sale of the [product] would ultimately result in further infringement since the market for the [product] consists of individuals trained to use the product in an infringing manner." *Id.* The court disagreed, reasoning that providing "instruction to its customers" to not use the device in an infringing manner was less intrusive and "sufficient to prevent future infringement." *Id*. at 364.

Avadel has proactively implemented various measures to stop sales for IH. LUMRYZ is distributed only through specialty pharmacies with whom Avadel works closely. Sullivan Decl. at ¶ 4. Prescriptions can be filled only for registered patients. *Id.* When a physician prescribes LUMRYZ, they must identify the indication for which it is being prescribed. *Id.* That prescription is then submitted to a specialty pharmacy. *Id.* The specialty pharmacies then have license to either fill or refuse the prescription. *Id.* Avadel has written letters to the pharmacies explaining the Court's injunction so that they know to decline to fill prescriptions for IH. *Id.* at ¶ 7, Exs. 1-3. Avadel has also worked with Pharmacy Benefit Managers (PBMs) and Group Purchasing Organizations (GPOs) so that they too know about the injunction and can help stop sales of LUMRYZ for IH. Divis Decl. at ¶ 3; Davis Decl. at ¶ 4, Ex. C. In addition to sending letters to prevent IH sales of LUMRYZ, Avadel developed a call script for staff who are trained to respond to prescriber questions with a reminder that Avadel is not permitted to sell LUMRYZ for anything other than the treatment of narcolepsy. Sullivan Decl. at ¶ 8, Ex. 4. While there have been a small number of sales for non-narcolepsy indications (including to patients prescribed LUMRYZ off-label before the injunction, which sales are allowed to continue), Avadel has repeatedly communicated its injunction to its specialty pharmacies and will keep investigating any possible

non-narcolepsy prescriptions. Sullivan Decl. at ¶¶ 6, 9.[1]

Given that backdrop, Jazz's allegations of irreparable harm and necessity are wholly inadequate, as Jazz has not even acknowledged—let alone addressed—the various protective measures implemented by Avadel. That is particularly troubling given that Avadel identified those measures to Jazz and its counsel. Avadel's counsel contacted Jazz's counsel on multiple occasions attaching its letters alerting the entities at issue of the injunction. Davis Decl. at ¶¶ 2-5, Exs. A-D. In short, because Jazz and its affiants simply ignore this aspect of the necessity inquiry, Jazz has not made an adequate showing that its sweeping injunction is necessary to prevent infringement.

The existence of Avadel's protective measures is particularly pertinent when the activity at issue is protected by the First Amendment, as here. *See infra* at § III.B.2.

3. Jazz Has Not Even Attempted to Show Irreparable Harm Caused by Approval for IH

Even ignoring the contingencies that undermine Jazz's arguments, Jazz's arguments also fail because it has not attempted to show any causal nexus between approval and any alleged harm. Jazz's claims of lost market share, price erosion, and reputational harm—which are all speculative—are not predicated on LUMRYZ's approval for IH, but on *actual IH sales*. But "entitlement to an injunction requires a showing that there is a 'causal nexus' between the alleged irreparable harm and the *enjoined activity*." *Jazz*, 136 F.4th at 1089. Jazz has failed to prove any here.

Further, Jazz's affiant suggests that Jazz would suffer financial harm from market share loss and price erosion, but does not provide any specifics. D.I. 747 at 16-18. Nowhere in its arguments does Jazz provide any suggestion of the amount of market share it stands to lose or

[1] If Avadel were to obtain FDA approval, Avadel would send new letters to the pharmacies, GPOs, and PBMs. Divis Decl. at ¶ 4. Although IH would no longer be "off-label," its use for IH would still be enjoined, setting aside for the moment the merits appeal and any motion by Avadel to lift the injunction. Avadel would therefore once again inform the relevant parties of the injunction so as to stop LUMRYZ prescriptions for any non-narcolepsy indication, including IH. *Id.*

price decrease it expects. This failure is especially notable given that an injunction requires not just harm, but ***irreparable*** harm, whereas lost sales, lost market share, and price erosion are all redressable with money damages. Jazz makes no effort to calculate such damages or show that they are incalculable. Indeed, Jazz relies on alleged harms it is suffering as a result of LUMRYZ's narcolepsy sales, such as [redacted]. D.I. 747 at 17. Jazz never demonstrates any such harms uniquely tied to Avadel's IH approval.

a. Jazz Cannot Show Any Non-Trivial Infringement

Jazz cannot show that there will be any non-trivial LUMRYZ sales for non-narcolepsy indications. As Jazz knows, Avadel's procedures for stopping such sales are extensive, *see supra* at § III.A.2. Jazz has no justification for making an unsupported assumption that approval for IH would necessarily lead to Avadel making, using, and selling LUMRYZ for IH. It will not, confirming the lack of a strong, causal nexus between the harm alleged and the injunction sought.

Jazz also argues that "[a]dding IH to [LUMRYZ]'s label will increase insurance coverage" (at 13-14), but that argument fails for the same reasons. Jazz contends that if LUMRYZ is approved for IH, then "PBMs would cover it" and there would be increased use. *Id.* at 14. But, if the injunction remains in place, Avadel will continue working with its specialty pharmacies, GPOs, and PBMs to prevent sales for IH, regardless of approval status or insurance coverage.

Jazz goes on to assert that "every sale" of LUMRYZ is a "lost sale" by Jazz (at 16), but that unsupported statement ignores the market realities. While Jazz argues that Avadel and Jazz are "two head-to-head competitors" (*id.*), there will likely be other competitors in the market. Jazz has publicly acknowledged as much in its SEC filings, explaining that they "expect competition from generic versions of sodium oxybate." D.I. 747-1 Jazz Ex. 18 at 23. Indeed, at least two companies have already filed ANDAs for generic versions of Xywav. *Id.* Thus, both are further along the regulatory process than LUMRYZ; one has even received tentative approval already. *Id.*

Beyond oxybates, Jazz also acknowledged that another company, Harmony Biosciences, has announced a phase three study for its IH treatment. *Id.* Each of these competing IH treatments could equally make sales that would otherwise be made by LUMRYZ, rather than Jazz. Thus, Jazz cannot blithely assert that each sale of LUMRYZ takes a sale from Jazz.

Jazz's arguments regarding alleged "reputational harm" (at 18) likewise fail. Jazz repeats the same argument it made previously—that if Avadel receives FDA approval for IH, Jazz will no longer be able to tout to the public that Xywav is the only FDA-approved drug for IH. This argument fails for several reasons. First, although the Court previously found that Jazz would suffer reputational harm, that finding was tied to "Avadel's entrance into the market." D.I. 665 at 22-23. The Federal Circuit found that such harm was insufficient to support the injunction because FDA submission (or even approval) does not qualify as "entrance into the market." *Jazz*, 136 F.4th at 1089. As the Federal Circuit concluded, "it does not follow that enjoining Avadel's application would be *necessary* to prevent infringement." *Id.* Second, Avadel's submission of an sNDA does not guarantee approval. And regardless of approval, Avadel will take steps to stop LUMRYZ from being sold for IH. As the only reputational harm Jazz identifies would allegedly stem from infringing sales for IH (at 18) those two harms rise and fall together. Because there will be no non-narcolepsy LUMRYZ sales, there will be no reputational harm to Jazz either.[2]

b. Jazz's Inducement Argument Ignores Avadel's Actions

Jazz uses inducement law to argue that "disseminating drug product labeling instructing a specific use means that the company marketing that drug product is liable for causing infringement of that use." D.I. 747 at 10 n.2. That argument misapplies the law and is inapposite to these facts.

[2] To the extent that Jazz would truly suffer some degree of reputational harm if LUMRYZ was merely *approved* for IH, it is hard to imagine how Jazz would not suffer even greater harm with the sleep community by keeping LUMRYZ from patients, particularly given the ODD designation.

With respect to the law, Jazz argues that updating the LUMRYZ label to include an IH indication would necessarily induce "physicians to prescribe and patients to use Lumryz for IH." D.I. 747 at 11. That is wrong. Induced infringement requires the "specific intent to encourage another's infringement and not merely . . . knowledge of the acts alleged to constitute inducement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (quoting *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990)). It is not enough to point to an indication on a drug label to show induced infringement. While *GlaxoSmithKline*, on which Jazz relies, shows that a label can be *evidence* of an intent to infringe, it explains that "[w]hen the alleged inducement relies on a drug label's instructions, '[t]he question is not just whether [those] instructions describ[e] the infringing mode, . . . but whether the instructions teach an infringing use *such that* we are willing to infer from those instructions an affirmative intent to infringe the patent.'" *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1333-34 (Fed. Cir. 2021) (*quoting Eli Lilly & Co. v. Teva Parenteral Med., Inc.*, 845 F.3d 1357, 1368 (Fed. Cir. 2017)).

Here, Jazz has not provided any basis to infer an intent to infringe by Avadel in the hypothetical world where Avadel's IH clinical trial is successful, FDA approves LUMRYZ for the treatment of IH, and the label is revised in some fashion. Jazz's expert declarant, Dr. Bogan, likewise focuses only on a revised LUMRYZ label and fails to take into account Avadel's fulsome preventative measures which negate any alleged specific intent. *See infra* at § III.A.4.b. Indeed, Avadel has scrupulously complied with the Court's order, including by informing all specialty pharmacies, PBMs, and GPOs, to prevent infringing sales. *See supra* at § III.A.2.

Jazz's cited case law (at 4-5) does not instruct otherwise.[3] In *National Instruments*, the

[3] Jazz also cites to *Trans-World* and *Kaspar* but both are inapt since neither involved an injunction that restrained non-infringing activity. *Trans-World*, 750 F.2d 1552, 1564 (Fed. Cir. 1984); *Kaspar*, No. 95-1095, 1995 WL 662674 (Fed. Cir. Nov. 9, 1995).

Federal Circuit affirmed the district court's injunction barring sales of an entire software platform even though it had some insubstantial non-infringing uses because defendants did not demonstrate that they could "separate[e] out the infringing uses through reprogramming or the like." 113 F. App'x 895, 898-99 (Fed. Cir. 2004). In *Smith & Nephew*, the court held that enjoining some non-infringing conduct was necessary "to correct or mitigate the effects of past infringement" because "[m]erely modifying the instructional materials will not undo the years of infringement." 466 F. Supp. 2d 978, 989 (W.D. Tenn. 2006). Finally, in *Global Traffic*, the district court enjoined sales of certain components of the infringing devices because the defendant was unable to track its component sales and did "not provide[] the Court with evidence" that it could "limit the distribution of its [infringing components]" so they would be sold only to such customers who would use them in a non-infringing manner. 2009 WL 10678424 at *14. None of those facts are present here. LUMRYZ is not approved for IH and has not been widely used or sold to treat IH. And Avadel is not just capable of separating out the different indications but is already doing so.

Jazz next points to Avadel statements describing IH as an "opportunity," but that is hardly a basis to enjoin Avadel from submitting an sNDA. To be sure, Avadel sees an opportunity for LUMRYZ to treat IH; otherwise it would not be pursuing clinical trials or opposing Jazz's injunction. FDA sees much the same opportunity, as shown by its recent grant of ODD to LUMRYZ based on the plausible belief that it is clinically superior to XYWAV for IH. But recognizing an "opportunity" is not the same as intending to infringe. Avadel will not actually make such sales unless the Court permits it—as it has repeatedly said in its marketing materials and public statements. Divis Decl. at ¶ 2. Given these effective steps that Avadel continues to take to prevent the making, using, and selling of LUMRYZ for IH, there is no strong causal nexus between Avadel's filing for approval and actual infringement. Jazz has failed to show that

preventing Avadel from filing that application with FDA is necessary to prevent infringement.

4. Jazz's References to "Marketing" Do Not Demonstrate Irreparable Harm From Applying for Approval to Treat IH

a. Marketing Does Not Provide A Basis For An Injunction

Jazz appears to argue that Avadel's seeking approval of LUMRYZ for IH should be enjoined because it will necessarily lead to infringing marketing. D.I. 747 at 9-14. But marketing—as opposed to sales—is not an independent basis for an injunction nor would it lead to irreparable harm. "Marketing" is not itself infringement. 35 U.S.C. § 271(a) (defining infringement as making, using, selling, offering to sell, or importing a patented invention).[4] The proper inquiry is whether enjoining an sNDA for IH is "necessary to prevent *infringement*," not to prevent *marketing*. The former is what the Federal Circuit instructed this Court to consider, *see Jazz*, 136 F.4th at 1089, and Jazz's marketing argument fails to address the relevant issue.

b. Avadel Will Not Market LUMRYZ for IH

Even if marketing forms part of the relevant inquiry, Jazz's argument (at 9-14) that approval for IH will necessarily lead to marketing also fails because Jazz once again disregards the actions Avadel has taken to date to prevent non-narcolepsy sales and improperly focuses on a future LUMRYZ label in isolation. The relevant evidence shows that Avadel does not market LUMRYZ for any non-narcolepsy indication and will continue to refrain from doing so as long as the Court's injunction remains in effect. Thus, no irreparable harm will come to Jazz.

[4] Nor could an IH indication on a future LUMRYZ label constitute an offer for sale, as any such label will not contain the price, and Avadel will make clear in its marketing materials that it does not sell—and is enjoined from selling—LUMRYZ for the treatment of IH. *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon, Corp.*, 420 F.3d 1369, 1376 (Fed. Cir. 2005) ("[A]n 'offer to sell' under section 271(a) … must communicate a manifestation of willingness to enter into a bargain, so made as to justify another person in understanding that his assent to that bargain is invited and will conclude it.") (cleaned up) (citation omitted); *Smith v. Garlock Equip. Co.*, 658 F. App'x 1017, 1028-29 (Fed. Cir. 2016) (concluding that for marketing materials to constitute an offer for sale they must be targeted to potential consumers and contain a price quotation).

First, even if LUMRYZ is approved for IH and the updated label is posted on FDA's website as Jazz alleges, Jazz admits that action will be taken by FDA, and not by Avadel. D.I. 747 at 12. The Court's order enjoins *Avadel* from marketing LUMRYZ for non-narcolepsy indications and thus any posting by FDA would not violate the injunction. D.I. 666 at 2.

Second, even if LUMRYZ is approved for IH and the revised label is disseminated by Avadel as Jazz argues, that would not overcome the other protective measures Avadel has taken to prevent marketing for IH. Even if LUMRYZ is approved for IH, LUMRYZ marketing materials will make clear that LUMRYZ is enjoined from being sold for any non-narcolepsy indications, including IH. Divis Decl. at ¶ 4. In such circumstances, the existence of the label alone cannot constitute marketing. *See Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1375 (Fed. Cir. 2022) ("[T]he language in [Defendant's] label that encourages, recommends, or promotes an infringing use without any additional evidence showing such an infringing use will in fact occur, is insufficient for a finding of direct infringement."); *Metacel Pharms. LLC v. Rubicon Rsch. Priv. Ltd.*, No. 21-19463, 2023 WL 5939903, at *4 (D.N.J. Sept. 12, 2023), *aff'd*, No. 2023-2386, 2025 WL 1178384 (Fed. Cir. Apr. 23, 2025) (explaining the proper inquiry looks at the "label itself, together with marketing materials"); *ZUP, LLC v. Nash Mfg., Inc.*, 229 F. Supp. 3d 430, 454 (E.D. Va. 2017), *aff'd*, 896 F.3d 1365 (Fed. Cir. 2018) (finding a third-party YouTube video that instructed how to infringe did not constitute marketing where the "entirety of [Defendant's] promotional materials encourage[d] customers to use the [product] in a noninfringing manner.").

Here, Jazz chose not to assert infringement under the Hatch-Waxman Act and 35 U.S.C. § 271(e)(2). *Supra* at § I. And the Federal Circuit recently explained that in evaluating a non-Hatch-Waxman case, the question of whether a party is encouraging infringement is not determined solely by examining the label language. *Amarin Pharma, Inc. v. Hikma Pharms. USA*

Inc., 104 F.4th 1370, 1379 (Fed. Cir. 2024); *Metacel Pharms.*, 2025 WL 1178384, at *3 ("Labels that '[m]erely describ[e] the infringing use ... will not suffice.'") (citation omitted). This distinction renders all of Jazz's caselaw inapposite. In a non-Hatch-Waxman case like this, the question is whether the "label *in combination* with [Defendant's] public statements and marketing materials" would "communicate to physicians and the marketplace" that a product will be marketed or offered for sale in an infringing manner. *Amarin*, 104 F.4th at 1379. This is because "[d]etermining what will, or would, happen when a product enters the market requires 'consideration of all the relevant evidence,' including the proposed label's instructions and physician practice" as well as past conduct. *Genentech*, 55 F.4th at 1379 (citation omitted). When considering Avadel's past statements that LUMRYZ is enjoined from non-narcolepsy indications and commitment to maintain those statements while the injunction is in effect, approval of LUMRYZ for IH will not necessarily lead to marketing of LUMRYZ for the treatment of IH.

B. Enjoining Avadel's sNDA Submission Would Significantly Harm Avadel

Unlike Jazz's speculative future harms, Jazz's overbroad injunction would harm Avadel in two immediate ways: (1) denying Avadel the opportunity to demonstrate LUMRYZ's clinical superiority to XYWAV for IH; and (2) infringing on Avadel's constitutional rights.

1. Enjoining Avadel's sNDA Submission Would Deny Avadel The Opportunity to Demonstrate Clinical Superiority

There should be no doubt as to Jazz's true motivation. FDA makes ODE determinations at the time of approval, and so if Avadel cannot file its sNDA for IH, there will be no final ODE determination for LUMRYZ in IH. 21 C.F.R. § 316.34. Given FDA's decision granting LUMRYZ ODE for narcolepsy on the basis of clinical superiority, Jazz does not want FDA to consider whether LUMRYZ is likewise clinically superior in IH and so should be granted ODE. Such a determination would be a major change in the record since the parties briefed Jazz's first

injunction request, even on top of other changes that have already occurred. And the changes Jazz ignores are indeed significant. First, Jazz recently failed in its lawsuit seeking to overturn LUMRYZ's ODE designation for narcolepsy. *See Jazz Pharms., Inc. v. Kennedy*, 141 F.4th 254 (D.C. Cir. 2025). Further, as Jazz is no doubt aware, LUMRYZ was recently awarded ODD for the treatment of IH. *See* § III.D, *infra*.[5] FDA found that LUMRYZ may make the same major contribution to IH patient care already established for narcolepsy—its once-nightly dosing improves patients' lives. Gudeman Decl. at ¶ 6; *infra* at § III.D.

Should Avadel complete its clinical study and file an sNDA for IH, FDA will then determine both whether to approve LUMRYZ for IH and, if so, whether to grant LUMRYZ ODE for IH. In granting ODD, FDA has already determined that it is plausible that LUMRYZ is clinically superior to XYWAV for IH based on its once-nightly dosing. FDA should be permitted to rule on whether that plausible hypothesis is confirmed so that Avadel can move this Court to modify the injunction on the basis of the public's interest in access to clinically-superior drugs.

Jazz does not want FDA to make that clinical-superiority determination. Which is why it filed suit against FDA. That is also why Jazz moved to enjoin Avadel from even seeking FDA approval for IH. And it is now why, after the Federal Circuit vacated and remanded, Jazz once again moves to enjoin that non-infringing activity. But that Jazz does not want something to happen does not make Jazz's requested injunction proper relief in a patent infringement case.

[5] By not addressing ODD in its opening brief, Jazz has waived any arguments in reply. *Air Canada & Aeroplan Inc. v. Localhost LLC*, No. 23-1177-GBW, 2024 WL 1251286, at *8 n.5 (D. Del. Mar. 14, 2024); *Int'l Constr. Prods. v. Caterpillar Inc.*, No. 15-108, 2024 WL 406433, at *2 (D. Del. Feb. 2, 2024). Jazz cited multiple public Avadel documents in support of its renewed injunction motion, including earnings calls, SEC filings, and press releases, but opted not to mention the ODD award to LUMRYZ for IH. Having so carefully monitored Avadel's filings, Jazz plainly knew about it: Avadel issued a press release one day after FDA's letter was received and nearly two weeks before Jazz filed its brief. Ex. 1 (6/5/25 Avadel Press Release).

Avadel should be able to petition FDA to seek approval for a drug that has the potential to greatly benefit the public. That protected speech will not harm or prejudice Jazz, as explained above. *See supra* at § III.A. Should Avadel's clinical trial fail or FDA reject Avadel's application, Jazz plainly will suffer no harm. But should FDA approve such an application and award LUMRYZ ODE status, Avadel is entitled to provide those facts to the Court pursuant to FED. R. CIV. P. 60 and demonstrate that the injunction as it currently stands is unjustified based on the same public interest considerations this Court already applied with respect to narcolepsy.

2. Enjoining Avadel's sNDA Submission Would Improperly Block Constitutionally Protected Conduct

There can be no doubt that precluding Avadel from filing an sNDA impedes core constitutionally protected conduct. Avadel has a First Amendment right to petition "administrative agencies" like FDA, and it would be "destructive of" that right to prohibit Avadel from advocating its "points of view" with FDA. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510-11 (1972). Jazz seeks to impose a naked prior restraint on that protected speech. A prior restraint is a "judicial order[] *forbidding* certain communications when issued in advance of the time that such communications are to occur," and a permanent injunction that "actually forbid[s] speech activities" is a "classic example[]" of a prior restraint. *Alexander v. United States*, 509 U.S. 544, 550 (1993) (citation omitted). As such, it bears a "heavy presumption against its constitutional validity." *N.Y. Times Co. v. United States*, 403 U.S. 713, 714 (1971).

Jazz must therefore show that the "evil that would result" from Avadel's submission to FDA is "both great and certain" and "cannot be mitigated by less intrusive measures." *CBS, Inc. v. Davis*, 510 U.S. 1315, 1317 (1994). Jazz does not even acknowledge that standard, let alone attempt to satisfy it. Jazz has therefore waived any basis to claim that its proposed injunction can pass constitutional scrutiny. *See Air Canada*, 2024 WL 1251286, at *8 n.5; *Int'l Constr.*, 2024

WL 406433, at *2 ("Arguments raised for the first time before a district court in a reply brief are deemed forfeited."). Nor can Jazz's proposed injunction hold up. Congress has affirmatively privileged the submission of drug applications, even infringing submissions, and Jazz concedes that the submission here is *non*-infringing. *Supra* at § I; 35 U.S.C. § 271(e)(2), (4). And Jazz cannot show that the result it predicts is "certain," or unable to be "mitigated" by the "less intrusive measures" described. *Supra* at § III.A. This is another reason the Court should deny Jazz's motion.

Even if this Court believes, contrary to Avadel's arguments, that an application will inevitably lead to marketing, it *still* must conduct a First Amendment analysis as to Jazz's requested injunction. At minimum, "[s]peech in aid of pharmaceutical marketing … is a form of expression protected by the … First Amendment" and therefore subject to "heightened judicial scrutiny." *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 557, 571 (2011). Such heightened scrutiny requires a "substantial" interest and a "measure is drawn to achieve that interest." *Id.* at 572. Jazz both waived any argument it satisfies this standard, and its overbroad injunction fails to do so.

Preventing Avadel from submitting an sNDA is a significant restriction on activity that is not just lawful, but constitutionally protected. And it is not necessary to prevent infringement. Avadel's current and future instructions to its pharmacies in particular, as well as to the GPOs and PBMs, informing them of the Court's injunction and instructing them that LUMRYZ cannot be sold for any indication other than narcolepsy will prevent infringement. No more is necessary.

C. The Balance Of The Equities Does Not Favor Jazz

Jazz argues that it will suffer harm from competing sales and that Avadel will suffer no harm whatsoever. Jazz is wrong. Jazz will not suffer any lost sales, price erosion, or reputational harm from a LUMRYZ sNDA requesting FDA approval for the treatment of IH. Nor will it suffer any of those harms if LUMRYZ is approved for that indication. Avadel is able to—and commits to—take steps to stop sales of LUMRYZ for the treatment of IH until and unless the injunction on

the making, using, or selling of LUMRYZ for the treatment of IH is lifted. *Supra* at § III.A.2. On the other, Jazz's attempt to foreclose FDA's consideration of ODE for IH and deny Avadel its right to petition the government causes real harm to Avadel. FDA already determined that LUMRYZ is clinically superior to Xyrem and Xywav for narcolepsy based on once-nightly dosing. Avadel expects that it will determine the same for IH for the same reason. Indeed, FDA has already awarded LUMRYZ ODD for IH on this basis. *See* § III.D, *infra*. FDA should be able to determine whether to award ODE, and if so, Avadel should have the ability to present that fact to the Court.

D. The Public Interest In Patient Health Weighs Heavily Against An Injunction

The public interest also favors allowing Avadel to seek approval for IH because LUMRYZ offers a potentially superior treatment. As the Court recognized, the "FDA's superiority determination strongly indicates that the public interest favors the availability of LUMRYZ for narcolepsy." D.I. 665 at 19. On June 4, 2025, FDA granted LUMRYZ ODD for IH "based on the plausible hypothesis that [LUMRYZ] may be clinically superior to the same drug(s) already approved for the same indication because [LUMRYZ] may provide a major contribution to patient care due to [LUMRYZ]'s once nightly dosing for patients with IH, a chronic sleep disorder that requires potentially lifelong treatment." Ex. 2 at 1 (FDA, June 4, 2025 Orphan Drug Designation).

Jazz makes two arguments. First, Jazz argues that the Court "already found 'the public interest weighs in favor of enjoining LUMRYZ in the IH market.'" D.I. 747 at 20 (citing D.I. 665 at 25-29). Second, Jazz cites to the Court's prior finding that "Avadel has not [and cannot] show[] that LUMRYZ offers any other distinct benefits to patients with IH." *Id.* 20 (citing D.I. 665 at 28). But FDA's grant of ODD for IH fundamentally changes the landscape and should alter those findings. Jazz's failure to address ODD suggests that it has no answer.

CONCLUSION

The Court should deny Jazz's request to enjoin any future LUMRYZ sNDA for IH.

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