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

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF MOTION FOR A PERMANENT INJUNCTION AND FOR AN ONGOING ROYALTY

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s

Cases

Rules and Statutes

Other Authorities

I. INTRODUCTION

Jazz seeks a limited injunction under 35 U.S.C. § 283 against Avadel's future infringement of the unit dosage form of claim 24 of U.S. Patent No. 11,147,782 ("the '782 patent")—both in the narcolepsy and idiopathic hypersomnia ("IH") markets.[1] Jazz does not seek to enjoin Avadel from continuing to make, use, or sell Lumryz™ for patients who, at the time of the injunction, have already been prescribed Lumryz. All factors support Jazz's request.

First, under Federal Circuit law, Avadel's infringement irreparably harms Jazz. Jazz is experiencing loss of market share to a direct competitor, price erosion, and reputational harm/loss of goodwill. Jazz has never licensed, and did not want to license, the '782 patent. Instead, Jazz is entitled to enforce claim 24 to protect its oxybate products, which in 2023, made up 48% of its revenue. There is also a causal nexus between Lumryz's infringing features and its demand. Claim 24 covers Lumryz as a whole; Lumryz cannot be sold without Jazz's invention.

Second, monetary damages are inadequate to compensate Jazz. As the Federal Circuit has recognized, the same evidence that supports Jazz's irreparable harm supports this factor.

Third, the balance of hardships favors Jazz. Jazz's hardships are listed above, and any hardship to Avadel is self-inflicted, particularly because it chose to launch its infringing product, at risk, despite the initiation of this suit. Thus, under Federal Circuit law, this factor favors Jazz.

Fourth, the limited injunction will not disserve the public interest. The Federal Circuit recognizes the strong public interest in enforcing patent rights, especially for pharmaceutical patents. Moreover, Lumryz is not more effective or safer than Jazz's oxybate products. In fact, Lumryz, due to its much higher sodium load, is less safe than Xywav. And Jazz has capacity to

[1] Evidence admitted at trial is of record. Jazz further relies on the exhibits attached hereto and the Declarations of P.J. Honerkamp ("Honerkamp Decl.") and Mark Rainey, Ph.D. ("Rainey Decl.") submitted herewith.

supply the entire market. There is also no alleged convenience benefit for Lumryz over Jazz's product for the IH market. Xywav is already FDA-approved for the once-nightly treatment of IH, and Lumryz is not even FDA approved for IH. Also, no existing Lumryz patient—with either narcolepsy or IH—will be impacted by the injunction.

Finally, Jazz requests that the Court award an ongoing royalty of 27% from the March 4, 2024 jury verdict through 2025, 13% from 2026 through 2032, and 3.5% from 2033 through February 2036 applied to future net revenues of Lumryz from: (1) the patients carved out of the permanent injunction; or (2) if the Court denies the injunction, all Lumryz patients in the U.S.

II. NATURE AND STAGE OF THE PROCEEDINGS

Before trial, Avadel stipulated to infringement of claim 24. Avadel's counsel made clear that claim 24 *is* Lumryz: "[A] viscosity enhancing agent [and] an acid wherein the suspending and viscosifying agent and the acidifying agent are separate and distinct from the immediate-release portion and the modified-release portion, that's [Avadel's] invention." Tr. 74:10-14; *see also* Tr. 74:19-21 ("[T]hose words describe our product because that's our invention, that's what they mean when they say we infringe."). Avadel's counsel thus framed "[t]he question for [the jury]" as "who made that invention? Did [Jazz] make that invention or did [Avadel] make that invention?" Tr. 74:23-25. The jury decided that Jazz made the invention; it returned a verdict of no invalidity for lack of written description or enablement and of no invalidity for improper inventorship. Per the Court's Order (D.I. 585), Jazz respectfully submits this brief in support of its motion for a limited permanent injunction and for an ongoing royalty.

III. THE COURT SHOULD GRANT THE LIMITED PERMANENT INJUNCTION

The "right to maintain exclusivity" is "a hallmark and crucial guarantee of patent rights deriving from the Constitution itself." *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 642 (Fed. Cir. 2015); *see also* U.S. Const. Art. I, § 8, cl. 8. "The courts have a long history of remedying

trespass on property rights—including patent rights—by removing the trespasser." *Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1338 (Fed. Cir. 2013). "Absent adverse equitable considerations, the winner of a judgment of validity and infringement may normally expect to regain the exclusivity that was lost with the infringement." *Edwards Lifesciences AG v. CoreValue, Inc.*, 699 F.3d 1305, 1314 (Fed. Cir. 2012). This District therefore routinely grants permanent injunctions. *See Natera, Inc. v. ArcherDx, Inc.*, No. 20-125, 2023 WL 9103876 (D. Del. Dec. 1, 2023); Ex. 1, *Wonderland Switzerland AG v Evenflo Co., Inc.*, No. 20-727, D.I. 281 (D. Del. June 7, 2023); *Vanda Pharms. Inc. v. Roxane Labs., Inc.*, 203 F. Supp. 3d 412 (D. Del. 2016); *Invista N. Am. S.A.R.L. v. M & G USA Corp.*, 35 F. Supp. 3d 583 (D. Del. 2014).

Courts "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. Jazz must show by a preponderance of the evidence that: (1) "it has suffered an irreparable injury;" (2) "remedies available at law, such as monetary damages, are inadequate to compensate for that injury;" (3) "considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted;" and (4) "the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

A. Avadel's Infringement Irreparably Harms Jazz

1. Jazz's lost market share to its direct competitor is irreparable harm

"That [Jazz] and [Avadel] are competitors and [Jazz] has lost market share strongly suggests irreparable harm." *Natera*, 2023 WL 9103876, at *3; *see also Broadcom*, 732 F.3d at 1338 (affirming that parties "were competitors and that Broadcom lost market share while Emulex gained it—thus Broadcom established irreparable harm").

Jazz markets the oxybate products Xyrem® and Xywav® (Tr. 465:8-18), which compete directly with Lumryz (Tr. 574-579; JTX113.11).[2] Avadel has and would continue to take market share from Jazz. Ex. 2 at 10-12; PTX300.14, 34; JTX129, Total Market Tab; PTX1899.22-23. Its "primary goal" is to "switch[]" Jazz patients to Lumryz. Tr. 524:24-25; *see also* JTX140.32 ("Initial launch focus on ~1600 higher volume oxybate prescribers and towards switch patients."). In July 2023, "74 percent of Lumryz's patient enrollment were patients that switched." Tr. 523:17-524:20; JTX122.43; *see also* PTX1901.1 ("The majority of . . . patients currently being treated with LUMRYZ are patients who switched from first generation oxybates."). And, in January 2024, Avadel reported Lumryz has the potential to gross $1 billion/year and take 50-60% of the oxybate-treated market. Tr. 525:16-527:25; PTX1899.7.

Since trial, Avadel reports that "the majority of patients [on Lumryz] are switch patients with more coming from the [Xywav] mixed salt." Ex. 2 at 10-12; *see also* Ex. 3 at 10 ("[T]he majority of our enrollments and patientship product being switch patients from the first generation oxybate more coming from Xywav than from Xyrem."). "[W]hen [Avadel] dug into the data, what [it] saw was the XYWAV patients tended to be diagnosed for a shorter period of time. They switched treatment sooner." Ex. 2 at 12. [redacted] Honerkamp Decl. at ¶¶ 25-26.

Xywav is the core of Jazz's sleep brand and the most valuable of Jazz's oxybate products, which together grossed $1.84 billion in 2023 (48% of Jazz's total revenue). Ex. 4 at 83. Xywav is the only low-sodium oxybate and the first and only FDA-approved IH treatment. Since its 2020

[2] Any argument that Jazz's competing products do not practice claim 24 is irrelevant. "[T]hat [Jazz] does not practice the invention does not disprove irreparable injury." *Natera*, 2023 WL 9103876, at *4. "Here, [Jazz] does have commercial activity, and the two companies are direct competitors. . . . This case is thus unlike the genre of cases dealing with non-practicing entities, since there is a clear record of commercial and irreparable harm to [Jazz's] business model." *Id.*

launch, Xywav sales have increased rapidly: $15 million in 2020, $535 million in 2021, $958 million in 2022 (Tr. 128:16-130:4; Ex. 5 at 81), and $1.272 billion in 2023 (Ex. 4 at 83).

Jazz facing competition from its own patented invention this early in Xywav's launch will irreparably harm Xywav's growth and impact Jazz's future oxybate business. In August 2021, Xywav became the first and only FDA-approved IH treatment. Tr. 92:17-21, 520:5-8. IH is a rare and chronic sleep disorder, separate from narcolepsy, that causes excessive daytime sleepiness even after a full night of good sleep. Tr. 92:24-93:13. There are approximately 45,000 patients diagnosed with IH. Tr. 519:17-24. The number of patients taking Xywav for IH has increased dramatically year-over-year—leaping 59% from 2022 to 2023. Ex. 4 at 83.

Avadel sees this new IH market as holding "a lot of opportunity" because "there's a robust patient population . . . with only one currently FDA approved treatment, [Xywav]." Ex. 2 at 23. Avadel is thus pursuing FDA approval for Lumryz to treat IH. Tr. 519:17-19. And notably, Avadel has already "seen claims and requests coming in for off label uses of LUMRYZ" for IH. Ex. 3 at 19. Thus, even though Lumryz is not FDA approved for IH, it has already begun taking Jazz's market share for that disorder. It is currently a "crucial inflection point in the development of the [IH] market," and Avadel should not be permitted to "capture and define the market with pirated technology." *Illumina, Inc. v. Qiagen, N.V.*, 207 F. Supp. 3d 1081, 1093 (N.D. Cal. 2016). Avadel is taking Xywav's market share in both the narcolepsy and IH markets before it can fully establish itself. This injury is impossible to quantify and is irreparable harm. *See Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344 (Fed. Cir. 2013) ("Irreparable injury encompasses different types of losses that are often difficult to quantify.").

2. Jazz not licensing the '782 patent further evidences irreparable harm

The "strong" evidence of irreparable harm due to loss of market share to a competitor is "especially true where [the patentee] has not licensed competitors to sell [the infringing product]."

Natera, 2023 WL 9103876, at *3; *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed. Cir. 2012) ("The district court correctly found Presidio's unwillingness to license favored finding irreparable injury.").

Jazz has never licensed the '782 patent and was not interested in licensing it to Avadel. Tr. 105:15-107:3; 571:23-572:9. This makes Jazz's "strong" showing of irreparable harm given its lost market share to Avadel "especially true." *Natera*, 2023 WL 9103876, at *3.

3. Price erosion caused by Avadel's infringement is irreparable harm

"[I]rreversible price erosion" is irreparable harm. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006); *see also Edwards Lifesciences AG v. CoreValve, Inc.*, No. 08-91, 2014 WL 1493187, at *6 (D. Del. Apr. 15, 2014). Avadel's infringement is causing Jazz's Xywav price to erode. Jazz and Avadel make revenue by gaining reimbursement from insurance companies. Tr. 534:7-11; Honerkamp Decl. at ¶¶ 27-29. Avadel has obtained, and is attempting to obtain, preferred status with various pharmacy benefit managers ("PBMs") (*see* PTX1901.1), through increased rebates back to the PBMs. Insurance companies contract with PBMs to, among other things, negotiate prices for patients covered by an insurance plan. The PBMs, in turn, negotiate with drug companies for rebates from the drug companies' Wholesale Acquisition Cost ("WAC"), which is the price paid for drugs purchased from the drug manufacturer. Honerkamp Decl. at ¶¶ 28-29. Avadel's infringement, and resulting negotiations with PBMs, has caused, and would continue to cause, Xywav prices to erode.

As of January 2024, Avadel had "[c]ontracts now in place with all 3 PBM owned GPOs (Ascent/ESI, Zinc/CVS and Emisar/Optum)," and "LUMRYZ moved to preferred status within the CVS commercial formularies and Optum Select." PTX1901.1 [redacted]

Ex. 6. [redacted] Ex. 7 at AVDL_01429299. [redacted] Ex. 8. [redacted] Ex. 9 at AVDL_01432795. [redacted]

4. The harm to Jazz's reputation and goodwill is irreparable

Reputational harm is not quantifiable and is therefore irreparable harm. *See, e.g.*, *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930-31 (Fed. Cir. 2012); *Douglas*, 717 F.3d at 1344-45. Jazz has suffered and would continue to suffer reputational harm and loss of goodwill from: (1) losing its exclusive status as the market leader in sleep and (2) Avadel's marketing campaign for its infringing product and against Jazz's products, particularly low-sodium Xywav.

(i) Loss of status as the exclusive market leader is irreparable harm

Before Lumryz's launch, Avadel acknowledged Jazz was "the market leader in sleep." Tr. 484:17-485:4; PTX338.4. Avadel's use of Jazz's patented invention to take market share from Jazz will irreparably harm that status and Jazz's reputation. Avadel expects to become the oxybate leader for narcolepsy. Ex. 2 at 14-15 ("[W]e did six different quant demand market research studies where LUMRYZ was given the highest market share in the [oxybate] category between 40 and 61 percent over six different studies."); *see also* Tr. 516:24-517:8 (Avadel "expect[s] Lumryz to get somewhere between 50 and 60 percent."); JTX119.137; PTX300.14. This would preclude Jazz from being able to market to physicians and patients that Jazz alone is the market leader. Honerkamp Decl. at ¶ 35. It is "difficult[to] quantify[ ] the effect on reputation and business due to [Jazz] being precluded from marketing to potential and existing customers that it is the exclusive market leader." *Celsis*, 664 F.3d at 930; *Douglas*, 717 F.3d at 1344 ("Even absent consumer confusion . . . there can still be harm to a company's reputation, particularly its perception in the marketplace by customers, dealers, and distributors."). Exclusivity "is an intangible asset that is part of a company's reputation," and Avadel would continue to harm Jazz's reputation with its further infringement. *Douglas*, 717 F.3d at 1345.

(ii) Avadel's marketing strategy for its infringing product, and against Xywav, is irreparable harm

Avadel's marketing focuses on Lumryz's purported clinical superiority over Jazz's products. JTX63; JTX85.13-14, 18; JTX86.5-6; JTX138.17-18; JTX140.4; JTX300.7, 26-29. Courts have found such marketing causes irreparable reputational harm. *See EZ Gard Indus., Inc. v. XO Athletic Co.*, No. 07-4769, 2008 WL 1827490 (D. Minn. Apr. 23, 2008), *aff'd,* 302 F. App'x 920 (Fed. Cir. 2008) (finding patentee "will likely suffer irreparable harm absent an injunction" to its reputation and goodwill where infringer marketed its product as "superior").

Avadel also uses a publication and sales campaign with the aim of damaging the reputation of Jazz's Xywav. The FDA found that Xywav's significantly lower amount of sodium is "safer" for "all patients with narcolepsy." JTX112.31-32. Jazz relies upon the FDA's finding in its Xywav marketing. Honerkamp Decl. at ¶ 34. Avadel, however, downplays the FDA's sodium finding and instead tells patients and prescribers that sodium is not harmful to patients in order to better position Lumryz (high-sodium) against Xywav. JTX63.3 (responses to doctors' objections to Lumryz high-sodium content); JTX122.32 ("Competitive messaging continues to focus on sodium."); JTX142.34 (attempting to distinguish Lumryz's ODE from Xywav's ODE); PTX300.46. Avadel even funded an article published in *Sleep Medicine* titled "The sodium in sodium oxybate: is there cause for concern?" (Ex. 11), which it uses in public messaging to downplay the dangers of excess sodium intake (PTX1899.41-42). This campaign damages the reputation and goodwill of both Jazz as a patient-focused company designing safer drugs and the reputation of Xywav as a safer oxybate treatment than high-sodium oxybates. Since trial, Avadel continues this disparaging campaign. Ex. 2 at 10-12 ("[I]f you think about the impact of the salt, magnesium, calcium, potassium, or sodium, that really doesn't do anything different to the narcolepsy outcome for the GHB."). Without being enjoined, Avadel would continue to irreparably harm Jazz's reputation and customer goodwill. Honerkamp Decl. at ¶ 34.

5. A causal nexus exists between Avadel's infringement and Jazz's harm

Jazz must show a "causal nexus relates the alleged harm to the alleged infringement." *Apple*, 809 F.3d at 639. The infringing features need not be the "exclusive or predominant reason" that consumers buy the infringing product, there only needs to be "some connection between the patented features and the demand for the infringing products." *Id.* at 642.

The causal nexus inquiry here is not a close call. Lumryz cannot be sold without the invention of claim 24. Claim 24 covers Lumryz as a whole, as opposed to individual features of

Lumryz. Avadel's counsel admitted this at trial. *See supra* at § II. Unrebutted technical expert testimony at trial also demonstrates that Lumryz as a whole is a commercial embodiment of claim 24. Tr. 391:8-22. Thus, causal nexus and consumer demand are apparent from the fact of infringing sales. *See Genband US LLC v. Metaswitch Networks Corp*., 861 F.3d 1378, 1384-85 (Fed. Cir. 2017); *see also* JTX63.5 ("the blend of immediate-release and controlled-release particles [] allows for the single bedtime dose"); JTX132.1 ("In total, 92 (93.9%) participants preferred the once-nightly dosing regimen of ON-SXB to twice nightly."); JTX142.6.

Indeed, Avadel has never contended that there would be *any* demand at all for Lumryz if the infringing technology, the unit dosage form itself, was not used by Avadel. Jazz's patented unit dosage form is the foundation of Lumryz and Lumryz could not be marketed without Jazz's invention. Thus, there is a clear causal nexus between the infringement and Jazz's injuries.

B. Monetary Remedies Will Not Adequately Compensate Jazz

"[I]nadequacy of remedies available at law[] is nearly indistinguishable from irreparable injury." *Natera*, 2023 WL 9103876, at *4. "[L]oss of market share, brand recognition, and customer goodwill . . . may frequently defy attempts at valuation, particularly when the infringing acts significantly change the relevant market." *i4i Ltd. P'ship v. Microsoft, Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010). As explained below, monetary remedies are inadequate here.

First, "[m]onetary damages are inadequate to compensate [Jazz] here because [Jazz] would be forced to compete against a rival gaining market share with [Jazz's] technology." *E.I DuPont de Nemours & Co. v. Unifrax I LLC*, No. 14-1250, 2017 WL 4004419, at * 5 (D. Del. Sept. 12, 2017), *aff'd*, 921 F.3d 1060 (Fed. Cir. 2019); *see also supra* at § III.A.1-2.

Second, Jazz has already been harmed by the price erosion caused by Avadel's infringement. *See supra* at § III.A.3. This harm would only be exacerbated in the future. [redacted] Avadel has continued

negotiating with PBMs, and recently announced that it is up to 80% of commercially insured lives covered (Ex. 2 at 5), [redacted] (Ex. 12 at AVDL_01432657). Avadel's infringement would continue to erode the price of Xywav. Honerkamp Decl. at ¶ 33.

Third, legal remedies are "inadequate to compensate [Jazz] for at least the reputation loss [it] has suffered from [Avadel's] infringement." *See Douglas*, 717 F.3d at 1345; *see also supra* at § III.A.4. These concerns are particularly strong here because Avadel's primary business strategy is directed at taking Jazz's patients and disparaging Jazz's products along the way.

Fourth, the full extent to which Avadel would harm Jazz is yet unknown. The narcolepsy market is at a "crucial inflection point in the development of the market." *Illumina*, 207 F. Supp. 3d at 1093. The Xyrem AG launched in 2023 and multisource generics are expected to launch no later than 2026. The launch of Lumryz has also "significantly change[d] the relevant market" such that future monetary damages will be impossible to calculate. *See i4i*, 598 F.3d at 862.

Moreover, as explained above, Avadel is attempting to expand its FDA-approved indication for the infringing product to include patients with IH, for which Xywav is the first and only FDA-approved drug. An IH indication for Lumryz would also "significantly change the relevant market" as entry of a second FDA-approved IH treatment, particularly an oxybate, would cause irreversible and unquantifiable market changes. Avadel's efforts to gain an IH indication thus further muddy any chance at calculating the damages Jazz would suffer, and exemplify the irreparable harm Avadel would continue to cause without an injunction.

C. The Balance Of Hardships Favors Jazz

Avadel's infringement, and Jazz's resulting lost market share and being forced to compete against its own patented invention, "places a substantial hardship" on Jazz, which "strongly weighs in favor of an injunction." *See Apple*, 809 F.3d at 646. And here, the balance tilts even more strongly in Jazz's favor because any harm Avadel claims it would face was "almost entirely

preventable" and triggered by its "own calculated risk to launch its product pre-judgment" despite knowledge of Jazz's patent. *Sanofi*, 470 F.3d at 1383.

Avadel was well-aware of its alleged infringement of claim 24 by November 10, 2021. C.A. 21-1594, D.I. 1. It nonetheless took the calculated risk of launching Lumryz in June 2023 (PTX1977), and has continued to tout Lumryz's prospects despite full knowledge of claim 24. Ex. 13 at 13:22-25 ("THE COURT: [I]s your client willing to stay the launch of the product until both cases are resolved? MR. YUE: We're not, Your Honor."); Ex. 14 at 3 ("A final approval will then be followed by a launch that is expected no later than Q3 of 2023."); Ex. 2 at 30 (touting Lumryz as a "$1,000,000,000 product opportunity"). Moreover, while Avadel did not present any evidence of a non-infringing alternative to claim 24 at trial, Avadel has purported to have invented other unit dosage forms that would *not* infringe Jazz's claim 24, but it is still choosing to market an infringing unit dosage form—and also chose to launch that infringing unit dosage form, at-risk, before this litigation was resolved. Avadel elicited testimony from both of its purported "inventors" on U.S. Patent No. 10,272,062, which was marked as JTX260. *See, e.g.*, Tr. 318:16-319:23, 656:24-657:14; *see also* Tr. 262:2-263:22 (Dr. Guillard confirming that he believed "everything in [the '062 Patent] to be true and accurate"). The '062 Patent unequivocally discloses that the "*first* principal structural embodiment" of Avadel's formulation does *not* include a viscosity enhancing agent or an acid. JTX260.62 at 23:54-63 (emphasis added). Those two ingredients, which are elements of claim 24, are not included until the "*second* principal structural embodiment" of Avadel's formulation. JTX260.62 at 23:64-24:7 (emphasis added). Moreover, Avadel purports in its '062 Patent to be able to package its microparticle formulation in "other suitable discreet packaging units" than a sachet, which is also an element of claim 24. JTX260.66 at 31:56-63. Avadel's choice to infringe further tips the balance in Jazz's favor. *See Sanofi,* 470

F.3d at 1383; *Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1329-30 (Fed. Cir. 2008) (holding that district court did not "abuse[] its discretion in relying on [patentee's] argument that a non-commercial straight nail depicted in a [defendant's] patent application" was a possible alternative and weighed in patentee's favor on this factor).

Any argument that this factor should favor Avadel because Avadel is allegedly a small, one-product company, lacks merit. That is a choice Avadel made for itself. Its CEO confirmed that, at one point, Avadel had seven other products on the market. Tr. 478:23-479:3. Then, in 2019, Avadel decided to sell off those other products and focus on Lumryz. Tr. 479:4-7, 479:23-480:3. "One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *Windsurfing Intern'l, Inc. v. AMF, Inc.,* 782 F.2d 995, 1003 n. 12 (Fed. Cir. 1986) ("[T]hat an injunction might therefore put Downwind out of business, cannot justify denial of that injunction."); *see also Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1156 (Fed. Cir. 2011) ("A party cannot escape an injunction simply because it is smaller than the patentee or because its primary product is an infringing one."); *Evonik Degussa Gmbh v. Materia, Inc.*, No. 09-636, 2017 WL 3434156, at *3 (D. Del. Aug. 10, 2017) (factor favored patentee where infringer "clearly is a much smaller company" because "relative financial hardship is but one factor the Court considers"). And in any event, Avadel would still make money given the limited injunction.

D. The Injunction Would Not Disserve The Public Interest

"[T]he public interest *strongly* favors an injunction." *Apple*, 809 F.3d at 647 (emphasis in original). While "the public often benefits from healthy competition," it "does not benefit when that competition comes at the expense of a patentee's investment-backed property right." *Id.* "[T]he encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude." *Id.* Such exclusionary rights are particularly

important for innovation leaders like Jazz, which invests revenues and attracts investment based significantly on its reputation and goodwill to develop medicines for the public's benefit. *Sanofi*, 470 F.3d at 1383–84 ("[T]he significant public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents tips the scales in favor of [patentee]."). Here, the patented invention is the key to Lumryz's success (Tr. 596:8-13), and it is the result of Jazz's long-standing investment in developing new technologies. The public has a strong interest in promoting and protecting such investment.

Jazz's products can fully meet the market's need for oxybate treatment of narcolepsy and IH if Lumryz is enjoined (Ex. 15 at JPION00523193), and as explained below they are (at minimum) an appropriate substitute for Lumryz. Indeed, Avadel cannot show that the injunction seeks to limit access to Lumryz to "patients who cannot be helped by [Jazz's products]." *See Edwards Lifesciences*, 2014 WL 1493187, at *11 (finding public interest in enforcing medical patent outweighed alleged public interest concerns for infringer subject to an accommodation for "patients who cannot be helped by [patentee's] devices"). In fact, the oxybate doses are so similar that Lumryz's labeling instructs that Jazz's patients are to switch to "the nearest equivalent [Lumryz] dosage in grams per night." JTX87.3. And all patients who are within the indication for Lumryz (adult patients with narcolepsy) are also within the broader indications for Jazz's products. *Compare, e.g.*, JTX87.2 *with* Ex. 16 at JPION00472953; Ex. 17 at JPION00472918. Courts find injunctions appropriate in similar circumstances. *See supra* at § III; *see also Celsis*, 664 F.3d at 932; *Amgen, Inc. v. F. Hoffman-La Roche Ltd.*, 581 F. Supp. 2d 160, 213 (D. Mass 2008); *Schneider (Europe) AG v. SciMed Life Sys., Inc.*, 852 F. Supp. 813, 850-51 (D. Minn. 1994), *aff'd,* 60 F.3d 839 (Fed. Cir. 1995); *Howes* v. *Med. Components, Inc.,* 741 F. Supp. 528, 534-35 (E.D. Pa. 1990).

Jazz's products are more established than Lumryz. Avadel itself called Jazz "the market leader in sleep." Tr. 484:17-485:4; PTX338.4. Insurance coverage for Jazz's products meets the market's needs. Over 90% of commercially covered lives have coverage. Honerkamp Decl. at ¶ 27. By contrast, Lumryz is accessible to about 80% of commercially covered lives. Ex. 2 at 5.

Any argument that an injunction is improper because some physicians and patients might prefer to have the choice of Lumryz is a red herring. "[E]liminating a choice of drugs is not, by itself, sufficient to disserve the public interest." *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1381 (Fed Cir. 2017). In any event, the requested injunction carves out patients already prescribed Lumryz. And by the time of the injunction hearing, Avadel will have had a year since the launch of Lumryz to market its drug product to any patients who receive an alleged benefit from Lumryz.

Avadel also acknowledges that the FDA has not found Lumryz to be safer or more effective than Jazz's products. Tr. 491:12-492:5. In fact, Avadel and its expert conceded that, in at least some patients, Lumryz may not be safe due to its high sodium content. Tr. 640:17-641:2; *see also* JTX87.1 (high sodium warning).

In opposition, Avadel may try to rely on, as it did at trial, the FDA's finding on Orphan Drug Exclusivity that Lumryz's once-at-bedtime dosing is purportedly a major contribution to patient care over Xyrem and Xywav. Tr. 492:21-493:3. But the FDA made clear that its finding was not based on better safety or efficacy. JTX112.32; Tr. 103:11-14, 491:12-492:5.

Moreover, the FDA's clinical superiority finding—which Jazz disagrees with and is challenging in a separate proceeding—is narrow. *First*, it is cabined to the *narcolepsy* market (JTX112.3), where Jazz's products are dosed twice-nightly. It is entirely irrelevant and inapplicable to the *IH* market, where Xywav is already FDA-approved for the once-nightly

treatment of IH. Ex. 16 at JPION00472955. Thus, there can be *no* argument that Lumryz will offer benefits to IH patients comparable to those it purportedly offers to narcolepsy patients.

Second, even in narcolepsy, the clinical superiority finding was not for "the entire patient population for which [Lumryz] is intended." JTX112.32. Instead, FDA "acknowledge[d] that the sodium content of Lumryz raises the same safety concern that was present for Xyrem and that is not present with Xywav." *Id.* Therefore, the FDA narrowly concluded that, "[f]or narcolepsy patients *who are not sensitive to sodium intake*, OOPD concludes that a once-nightly dosed oxybate drug will provide a significant therapeutic advantage." JTX112.33 (emphasis added). On the other hand, "[f]or narcolepsy patients *who are sensitive to sodium*, healthcare practitioners would need to weigh the benefits of once-nightly dosing against the severity of the patient's sodium sensitivity and the nature of their comorbidities to determine whether, in the practitioner's judgment, use of Lumryz or Xywav was appropriate." *Id.* (emphasis added). And while the FDA asserted that "a substantial number of narcolepsy patients" would benefit from once-at-bedtime dosing of Lumryz, it disclosed no data in support of that assertion. *See* JTX112.32-33. Instead, the only data showed that a substantial number of narcolepsy patients are salt sensitive. JTX112.31; *see also* JTX112.32 (FDA noting that salt sensitive patients "may constitute a significant portion of those with cataplexy and excessive daytime sleepiness in narcolepsy"); Ex. 18 (FDA finding Xywav's sodium reduction "will be clinically meaningful in reducing cardiovascular morbidity in a substantial proportion of patients for whom the drug is indicated"). Nevertheless, Avadel is attempting to switch patients from the safer Xywav product.

E. Jazz's Limited Injunction Should Be Granted

Jazz seeks a limited injunction that is supported by all factors above. Avadel may continue making, using, and selling Lumryz: (A) for patients prescribed Lumryz as of the effective date of the injunction pursuant to an ongoing royalty to be determined (*see infra* § IV); (B) in currently-

ongoing clinical trials and studies; (C) to update data in old studies if necessary; and (D) to re-run necessary tests for quality control for regulators or customers. Thus, those patients who have already chosen to undergo treatment with Lumryz will continue to have access. Jazz only seeks to prevent further infringement by Avadel, including by enjoining Avadel from expanding its currently FDA-approved indications (e.g., to include IH). Such an injunction is necessary and in the public interest to prevent the irreparable harm Jazz has and would suffer through Avadel's continued infringement, especially in the IH market for which there is no clinical superiority finding (and no basis for one in the future). *See supra* at § III.D.

IV. THE COURT SHOULD GRANT AN ONGOING ROYALTY CONSISTENT WITH THE SCHEDULE PRESENTED AT TRIAL

An ongoing royalty is also equitable relief. *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1314-16 (Fed. Cir. 2007). It is appropriate where a jury verdict addresses only past infringement. *Telcordia Techs., Inc. v. Cisco Sys. Inc.*, 612 F.3d 1365, 1379 (Fed. Cir. 2010).

The jury awarded Jazz a 3.5% royalty rate for past damages. Jazz disagrees that the 3.5% (instead of 27%) rate is supported by the factual record, and will address that in its post-trial motion. Moreover, Jazz is entitled to future damages for infringing sales since March 4, 2024 applying at least the royalty rate schedule set forth by Dr. Rainey at trial, i.e., 27% through 2025, 13% from 2026 through 2032, and 3.5% from 2033 through February 2036. Tr. 590:12-591:5. Those rates should be applied to Avadel's *net* revenues from Lumryz sales—the applicable measurement of the royalty base that was uncontested by Avadel at trial. *See, e.g.*, Tr. 598:24-600:5; *see also* D.I. 580 at 8 (acknowledging a royalty base using *net* sales of Lumryz).[3]

[3] To the extent Avadel argues that the ongoing royalty rate should be applied to a base less than Avadel's net revenues in light of the jury's verdict, Jazz disagrees. The jury made a clear mistake relying on gross sales data from an incorrect (and truncated) timeframe, and no evidence in the record supports apportionment of the royalty base, especially where Avadel has admitted that claim 24 covers Lumryz as a whole. Indeed, Avadel did not cross Dr. Rainey on this point (*see*

Jazz presented unrebutted testimony from Dr. Rainey at trial. His damages analysis accounted for Avadel's past use of claim 24 (Tr. 568:5-569:2, 591:6-10), and he has since confirmed that his analysis of the applicable royalty rate schedule remains the same (*see* Rainey Decl.).[4] The '782 patent does not expire until February 2036. As such, any lesser ongoing royalty rates would ignore the incremental value of claim 24 to both parties and the continuing real-world harm to Jazz due to Avadel's ongoing infringement. Tr. 588:24-589:16, 592:15-593:4, 594:12-595:3, 596:14-598:7. At trial, Dr. Rainey explained how a 3.5% royalty rate would be wholly insufficient to compensate Jazz for Avadel's use of claim 24 through its expiration in 2036 [redacted] Tr. 593:11-594:7. As Dr. Rainey explained, [redacted] *Id.* This remains true if the hypothetical negotiation were to occur at the time of the jury's verdict. *See, e.g.*, *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1370 (Fed. Cir. 2017). In sharp contrast, [redacted] Tr. 594:12-596:2. All of this evidence was uncontested.

Courts consider the financial impact of depriving a patentee of exclusivity against its will. *Joyal Products* held an ongoing damages rate set at the infringer's profit margin was "equitable . . . in that it would not allow [the infringer] to profit from any further willful infringement, and,

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Tr. 600-607), and attorney argument is not evidence (D.I. 572 at 5). Jazz will address the jury's verdict regarding past damages (including the unsupported 3.5% royalty rate and royalty base used by the jury (i.e., *gross* sales through September 6, 2023 only)) in its post-trial motion.

[4] Avadel asked Dr. Rainey a limited number of questions even though it knew at the time it may not be able to present its own damages expert to rebut Dr. Rainey's royalty rate schedule and made the strategic choice not to use the deposition testimony of its expert at trial once the expert was determined to be unavailable.

further, would adequately compensate [the patentee] for being unwillingly deprived of its right to exclusivity." *Joyal Prods. v. Johnson Elec. N.A.*, No. 04-5172, 2009 WL 512156, *14 (D.N.J. 2009). Here, Jazz is not asking for a rate set at Avadel's profit margin. In fact, absent the injunction, Avadel would still stand to make billions under Jazz's requested rates. Jazz is merely asking for rates that fairly compensate it for Avadel's continued use of the invention of claim 24.

Moreover, "[t]he determination of an ongoing royalty rate, including whether it should be increased beyond the jury's verdict, is a matter within the district court's discretion." Ex. 19, *Depuy Synthes Prods., LLC v. Globus Med., Inc.*, No. 11-652, Slip Op. at 5 (D. Del. Mar 25, 2014) (citing *Paice*, 504 F.3d at 1314-15). Jazz disagrees that the factual record supports the jury's 3.5% rate, but in any event, "courts frequently impose a post-verdict ongoing royalty rate that is higher than the reasonable royalty found at trial for past infringement." *Telcordia Techs., Inc. v. Cisco Sys., Inc.*, No. 04-876, 2014 WL 1457797, at *4 (D. Del. Apr. 14, 2014) (0.64% royalty increased to 1% and 1.25%); *see also, e.g.*, *Arctic Cat*, 876 F.3d at 1370 (affirming doubling of ongoing royalty); Ex. 19, *Depuy*, No. 11-652, Slip Op. at 15 (15% royalty increased to 18%); *Joyal Prods.*, 2009 WL 512156 at *13 (8% royalty increased to 26%); *Creative Internet Adver. Corp. v. Yahoo!*, 674 F. Supp. 2d 847, 861 (E.D. Tex. 2009) (20% royalty increased to 23%); *Syntrix Biosystems v. Illumina, Inc.*, No. 10-5870, 2013 WL 3089448, at *2 (W.D. Wash. June 18, 2013) (6% royalty increased to 8%).

"Prior to judgment, liability for infringement, as well as the validity of the patent, is uncertain, and damages are determined in the context of that uncertainty. Once a judgment of validity and infringement has been entered, however, the calculus is markedly different because different economic factors are involved." *Amado v. Microsoft Corp.*, 517 F.3d 1353, 1362 (Fed. Cir. 2008) (citing *Paice*, 504 F.3d at 1315). Indeed, Avadel's counsel suggested that the then-

uncertain validity of claim 24 should factor into the jury's damages analysis. *See* Tr. 600:19-601:24. But Jazz's bargaining position has now strengthened because, for example, Avadel's continued infringement of valid claim 24 is now willful, Avadel seeks to use Lumryz in future indications that will also willfully infringe claim 24, and Avadel has not attempted to reduce or avoid future infringement since the jury's verdict by redesigning Lumryz. *See, e.g.*, *Telcordia*, 2014 WL 1457797, at *5 (awarding increased ongoing royalty as "appropriate premium for Cisco's continued willful infringement"); *Syntrix Biosystems*, 2013 WL 3089448, at *2 (Defendant "has no readily apparent alternative if it seeks to continue its production and sale of the infringing product.").

For all of these reasons, Jazz requests an ongoing royalty of 27% from March 4, 2024 through 2025, 13% from 2026 through 2032, and 3.5% from 2033 through February 18, 2036 (the patent's expiry) applied to the future net revenues of Lumryz derived from: (1) sales to patients carved out of the injunction; or (2) if the Court denies the injunction, all Lumryz sales in the U.S.[5] But to be clear, Jazz's requested ongoing damages rates would not make it whole. Indeed, for determining post-verdict damages, Jazz cannot account for and is not seeking a higher ongoing royalty rate for its losses for having to directly compete with its own patented invention, price erosion, or the harm to its reputation and goodwill.

V. CONCLUSION

For the reasons set forth above, Jazz respectfully requests the Court grant the limited permanent injunction and ongoing royalty requested herein.

[5] Either way, Jazz is entitled to an ongoing royalty for infringing sales after the jury's verdict. Jazz will also seek supplemental damages and accounting for infringing sales through the date of the verdict (as well as other damages remedies) in its post-trial motion. *See* D.I. 585, ¶¶ 5-6.

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April 12, 2024

CERTIFICATE OF SERVICE

I hereby certify that on April 12, 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 April 12, 2024, upon the following in the manner indicated:

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