IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	C.A. No. 21-691-GBW [redacted]
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendants.	C.A. No. 21-1138-GBW [redacted]
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendants.	C.A. No. 21-1594-GBW [redacted]

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MEMORANDUM OPINION

August 27, 2024
Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

On May 12, 2021, Plaintiffs Jazz Pharmaceuticals Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Plaintiffs" or "Jazz") sued Defendant Avadel CNS Pharmaceuticals LLC ("Defendant" or "Avadel") for patent infringement. D.I. 1. Prior to trial, Avadel stipulated that its product, Lumryz, infringed claim 24 of U.S. Patent No. 11,147,782 ("the '782 patent"). Shortly thereafter and following a one-week trial, the jury returned a verdict of no invalidity for lack of written description or enablement and no invalidity for improper inventorship.[1] Now pending before the Court is Jazz's Motion for a Permanent Injunction and for an Ongoing Royalty. D.I. 586.[2] Avadel opposes the Motion for a Permanent Injunction and contends that Jazz is not entitled to an ongoing royalty or, alternatively, is entitled to a royalty at an ongoing rate of 3.5%. D.I. 601 at 1-2. The Court held a hearing on the Motion on June 6, 2024.[3] Having reviewed the Motion and all related briefing, the Court hereby **GRANTS-IN-PART** and **DENIES-IN-PART** Jazz's Motion as follows: (1) Jazz's request for a limited permanent injunction prohibiting Avadel from seeking FDA approval and marketing Lumryz for the treatment of idiopathic hypersomnia ("IH") is **GRANTED**; (2) Jazz's request for a limited permanent injunction prohibiting the use of Lumryz for new patients in the narcolepsy market is **DENIED**; and (3) Jazz's motion for an ongoing royalty for future infringement in the narcolepsy market is **GRANTED**, pending additional briefing on the appropriate rate.

[1]Trial Tr. ("Tr.").
[2]All D.I. cites in this Opinion refer to the docket in Case No. 21-cv-00691-GBW.
[3]Permanent Injunction Hearing Transcript ("P.I. Tr.").

I. LEGAL STANDARD

"According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief." *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391, 126 S.Ct. 1837, 164 L.Ed.2d 641 (2006). Under this four-factor *eBay* test, a plaintiff must show by a preponderance of the evidence: "(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." *Id.*

II. ANALYSIS

1. Permanent Injunction

Jazz seeks a limited permanent injunction to bar the marketing and sale of Lumryz in two markets: the narcolepsy and IH markets. D.I. 587 at 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. *Id.* For the following reasons, the Court grants a limited injunction prohibiting Avadel from seeking FDA approval and marketing Lumryz for the treatment of IH. With respect to the market for narcolepsy, however, Jazz has not shown that it is entitled to an injunction restraining the use or sale of Lumryz for new narcolepsy patients. To compensate Jazz for Avadel's continued infringement in the narcolepsy market, the Court grants Jazz's request for ongoing royalties at a rate to be determined for any future infringing sales of Lumryz to patients with narcolepsy.

A. The *eBay* Factors Weigh Against Enjoining Lumryz for Narcolepsy Treatment.

1. *Irreparable Harm*

a. *Jazz established that it suffered some irreparable harm through past loss of market share and price erosion.*

To show irreparable harm, a patentee must prove "1) that absent an injunction, it will suffer irreparable harm, and 2) that a sufficiently strong causal nexus relates the alleged harm to the alleged infringement." *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012). Jazz contends that the prescription of Lumryz for narcolepsy has and would continue to cause Jazz irreparable injury by limiting its market share, eroding the prices of its oxybate products, and damaging its reputation as a "market leader" in narcolepsy treatment. D.I. 587 at 3-8.

The Court agrees that Avadel's infringement has caused Jazz to suffer loss of market share. *See id.* at 3-5. Indeed, there is no dispute that Lumryz competes directly with Jazz's oxybate products in the narcolepsy market, and Avadel's CEO, Gregory Divis, testified during trial that one of Avadel's "primary goals and strategies" is to target Jazz customers by educating physicians on the benefits of switching patients from Xyrem and Xywav to Lumryz. Tr. 501:1-11, 524:21-23; P.I. Tr. 13:14-23 (noting that Avadel's marketing targeted prescribers and "advocated for them to switch patients from Jazz's products to Lumryz"). Avadel's internal reporting shows that Avadel succeeded in its efforts to switch Jazz patients to Lumryz, as approximately 74% of patients on Lumryz in 2023 were "switch patients with more coming from the [Xywav] mixed salt." Tr. 523:17- 524:20; Jazz Ex. 2 at 10-12. Jazz's internal records similarly found that prescriptions for Lumryz were "coming from switched patients instead of discontinued Jazz patients." P.I. Tr. 14:4-21; Honerkamp Decl., ¶¶ 25-26.

[redacted] *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006) (finding irreparable injury where patentee was "forced to offer discounted rates and price concessions to third-party payors, such as health maintenance organizations, in order to keep [its product] on a favorable pricing tier, which governs what consumers pay for that drug").

Because Jazz and Avadel continue to compete directly in the narcolepsy market, the evidence that Avadel negotiated PBM agreements to [redacted] coupled with evidence that Jazz prioritized marketing campaigns aimed at switch patients "strongly suggests irreparable harm." *Natera Inc. v. ArcherDx, Inc.*, No. 20-CV-125-GBW, 2023 WL 9103876, at *3 (D. Del. 2023)(finding irreparable harm where patentee and infringer are direct competitors

and patentee has lost market share due to competition); *see also Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed. Cir. 2012) ("Direct competition in the same market is certainly one factor suggesting strongly the potential for irreparable harm without enforcement of the right to exclude."). Moreover, as Avadel recently reported that Lumryz has the potential to take 50-60% of the oxybate-treated market, there is at least some continued risk of loss of market share and price erosion if Avadel's use of Lumryz is not enjoined. *See* Tr. 525:16-527:25.

Nevertheless, Jazz's claims of irreparable harm are undermined to a degree by Jazz's public statements and filings which attribute some of Jazz's market share loss and price erosion to generic competition. Jazz admitted in recent SEC filings, for instance, that "a significant percentage of the prescriptions written for Xyrem" will be filled with generic manufacturers. Jazz Ex. 4 at 17, 36. While Jazz conceded during the Permanent Injunction Hearing that "some of the lost sales of Xyrem are coming from generic sales," Jazz failed to quantify the effects of generic sales on the market for Xyrem and maintained that its licenses to generic manufacturers would not affect demand for Xywav. P.I. Tr. 51:16-24 (arguing that does "not touch Xywav; it has nothing to do with Xywav"). Yet, in its SEC filings, Jazz recognized that generic oxybate sales "have negatively impacted and ***are expected to continue to negatively impact Xyrem and Xywav sales for patients with narcolepsy***." Jazz Ex. 4 at 17, 36 (emphasis added). In a recent 10-Q, Jazz similarly noted that "generic or AG high-sodium oxybate products or branded high-sodium oxybate entrants in narcolepsy, such as Avadel's Lumryz, have had and may continue to have the effect of changing payor or formulary coverage of Xywav or Xyrem in favor of other products, and indirectly adversely affect sales of Xywav and Xyrem." Avadel Ex. 6 at 38; *see*

also Jazz Ex. 4 ("Generic competition can decrease the net prices at which branded products, such as Xywav and Xyrem are sold.").

Given these public statements, the Court cannot disregard Jazz's generic licenses merely because they cover "unrelated patents covering Xyrem and Xywav . . . ." D.I. 610 at 4. Indeed, the Federal Circuit has explained that "'[t]he fact of the grant of previous licenses, the identity of the past licensees, the experience in the market since the licenses were granted, and the identity of the new infringer *all may affect* the district court's discretionary decision concerning whether a reasonable royalty from an infringer constitutes damages adequate to compensate for the infringement.'" *Nichia Corporation v. Everlight Americas, Inc.*, 855 F.3d 1328, 1343-44, 122 U.S.P.Q.2d (Fed. Cir. 2017) (internal citations omitted & emphasis added). The district court in *Nichia* considered that the patentee granted licenses to "'significant competitors' who posed 'major threats' to [the] flagship products." *Nichia Corp. v. Everlight Elecs. Co.*, No. 02:13-CV-702-JRG, 2016 WL 310142, at *66 (E.D. Tex. Jan. 25, 2016), *aff'd sub nom. Nichia Corp. v. Everlight Americas, Inc.*, 855 F.3d 1328 (Fed. Cir. 2017). In finding that such evidence weighed against irreparable harm, the district court noted that the licenses changed the market by making available "multiple low-priced non-infringing alternatives." *Id.* The Federal Circuit found "no clear error in the district court's finding . . . ." *Nichia*, 855 F.3d at 1344.

Similarly, here, Jazz's licenses impact the narcolepsy market by allowing generic oxybate products to enter the market and compete directly with Xyrem, Xywav, and Lumryz. Dr. Rainey, Jazz's damages expert, recognized that the licenses would create "a highly competitive environment." Rainey Tr. 67:16-23. As highlighted above, Jazz's public filings also reveal that Jazz attributed some past and future market share loss and price reduction to this generic competition. *See supra* at 5. While Jazz's licenses to generic manufacturers do not establish a

lack of irreparable harm per se,[4] these licenses undermine Jazz's effort "to lay all the blame for lost sales and price erosion on Avadel." D.I. 587 at 4. Indeed, in requesting a limited injunction, Jazz failed to distinguish or quantify the past and future market share loss and price erosion caused directly by Avadel's infringement from the harm attributable solely to generic competition. *See* D.I. 610 at 3 (maintaining that the licenses are "irrelevant"). If Jazz expects that generic manufacturers will have significant implications for its oxybate products in the narcolepsy market, as Jazz's public filings imply, this refusal to meaningfully address the impact of generic competition, at the very least, casts doubt on Jazz's claim that enjoining Lumryz would remedy most or any of the asserted future injury. *See Nichia*, 2016 WL 310142, at *66 ("[B]ecause there are multiple low-priced non-infringing alternatives from competitors available to replace the accused [] products if such products were not available, Nichia America has failed to establish the amount of any additional supposed sales, if any, in the absence of competition from Everlight. Nichia has failed to establish it will suffer irreparable harm in the absence of an injunction.").

Further, Jazz contends that, absent an injunction, Avadel's marketing strategy will cause irreparable harm to Jazz's reputation and goodwill. D.I. 587 at 7-8. Yet, Jazz's claims of reputational harm are unpersuasive for at least three reasons. First, Jazz does not practice claim 24 of the '782 patent. While the Court agrees that irreparable harm may result even where the patentee does not practice the patent-in-issue,[5] "[r]eputational harm has previously been found to weigh in favor of injunctive relief where a plaintiff was itself practicing the patented invention

[4] *Acumed*, 551 F.3d at 1328.

[5] *See Presidio*, 702 F.3d at 1363 ("Even without practicing the claimed invention, the patentee can suffer irreparable injury.").

and where there was evidence of consumer confusion, a loss of product distinctiveness, or some risk to that plaintiff's status as an innovator." *Baxalta Inc. v. Genentech, Inc.*, No. CV 17-509-TBD, 2018 WL 3742610, at *11 (D. Del. Aug. 7, 2018). Where, on the other hand, the patentee does not practice the patent-at-suit, reputational harm is unlikely because "there is no risk that consumers will be confused about the source of the various products." *Id.* Second, as Jazz seeks to enjoin the use and sale of Lumryz for patients who have never been prescribed Lumryz, the injunction "will not stop doctors and patients from associating the innovation of [Lumryz] with [Avadel]." *Id.* And an injunction may even harm Jazz's reputation "if doctors know they're trying to keep Lumryz from [new] patients who can benefit from it quite a bit." *Id.* (internal citations omitted). Finally, as to Avadel's marketing of Lumryz as the superior treatment for narcolepsy, Jazz fails to show how Avadel's marketing campaign "is causing actionable reputational harm" when Avadel's superiority claims are supported by the FDA's ODE determination. *Abbott Cardiovascular Sys., Inc. v. Edwards Lifesciences Corp.*, No. CV 19-149 (MN), 2019 WL 2521305, at *22 (D. Del. June 6, 2019).[6]

b. *There is a sufficiently strong nexus between the irreparable harm and Avadel's infringement.*

Avadel contends that Jazz fails to establish a causal nexus between its alleged irreparable harm and Avadel's infringement. D.I. 601 at 11-13. The Court disagrees. The goal of the causal nexus requirement is to ensure that there is "*some* connection" between the harm alleged and the infringing acts, and the analysis of this requirement is a "flexible" one. *Apple, Inc. v.*

[6]Jazz also fails to present any evidence that Avadel's attempts to "downplay[] the FDA's sodium finding" is likely to result in irreparable harm. "[S]imply assert[ing]" that the marketing campaign will damage Jazz's reputation is not sufficient to establish irreparable harm. *Abbott*, 2019 WL 2521305, at *22; *but see Natera*, 2023 WL 9103876, at *3 (presenting evidence that customers "started asking questions why that happened is there something wrong with Natera").

Samsung Elecs. Co., 735 F.3d 1352, 1364 (Fed. Cir. 2013) (emphasis added). A patentee can therefore satisfy the nexus requirement in a number of ways—including, for example, "with evidence that a patented feature is one of several features that cause consumers to make their purchasing decisions[,]" "evidence that the inclusion of a patented feature makes a product significantly more desirable[,]" and "evidence that the absence of a patented feature would make a product significantly less desirable." *Id.*

Avadel argues, however, that Jazz must show that Lumryz "contains no feature relevant to consumers' purchasing decisions other than what the ['782] patent claims." D.I. 601 at 12. While "a finding that the competitor's infringing features drive consumer demand for its products satisfies the causal nexus inquiry[,] . . . this rule is neither categorical nor is it mechanically applied." *Endo Pharms. Inc. v. Amneal Pharms., LLC*, No. 12 CIV. 8060 (TPG), 2016 WL 1732751, at *5 (S.D.N.Y. 2016). Indeed, in cases where evidence of customer demand for an "infringing feature" has satisfied the nexus requirement, the relevant products have been "'complex, multi-featured' products." *Janssen Prod., L.P. v. Lupin Ltd.*, 109 F. Supp. 3d 650, 700 (D.N.J. 2014), *modified on other grounds*, No. 10-5954 (WHW), 2016 WL 1029269 (D.N.J. 2016); *Genband US LLC v. Metaswitch Networks Corp.*, 861 F.3d 1378, 1384 (Fed. Cir. 2017) ("The clarified standards set forth in *Apple III* and *Apple IV* govern the causal-nexus inquiry, at least in a multi-purchaser, multi-component situation in which only a component of a larger product or system is covered by the patent in suit."). Here, however, the infringing product is a pharmaceutical with a formulation that wholly infringes claim 24, which means that Avadel could not launch Lumryz as a commercial product without Jazz's invention. Under these circumstances, it is impracticable for Jazz to treat the infringing aspects of Lumryz "as a small

component part" of the overall drug.[7] Thus, the Court will not require Jazz to identify a non-prior art "feature" to satisfy the nexus requirement. *See also Janssen*, 109 F. Supp. 3d at 700 (noting that the nexus requirement does not require the patentee to "put forth [] evidence that the claimed, non-prior art elements of the [] patent are what drive sales or consumer demand" in the case of a process patent for a pharmaceutical, given that "it is not possible to separate the process for making the finished [] product from the product itself in evaluating consumer demand and nexus").

Rather, in this matter, the nexus requirement is satisfied by the indisputable evidence of direct competition between the parties. *See Endo Pharms.*, 2016 WL 1732751, at *5 ("Competition is logically tied to injury, since directly competitive companies are most likely to be rivals for market share, sales, customers, profits, business opportunities, goodwill, and brand power."); *see also Brocade Communications Systems, Inc. v. A10 Networks, Inc.*, 2013 WL 140039, *3-*4 (N.D. Cal. 2013) (finding that patentee "has proven a sufficient nexus between the established infringement and irreparable harm from the loss of its exclusive right to practice its patents"). Indeed, the weight of the evidence reveals that Avadel intended to introduce a competing product and recognized that Lumryz would impact the market demand and the prices for Jazz's products. *See, e.g.*, Jazz Ex. 2 at 23. Thus, the Court is persuaded that there is at least "some connection" between the alleged irreparable harm and Avadel's infringement.

In sum, Jazz has presented evidence of past harm due to market share loss and the erosion of the price for Jazz's products and has shown that a sufficient nexus exists between this harm

[7] And even if Jazz could treat the infringing elements as a "feature," the formulation of a pharmaceutical is typically what drives demand. D.I. 610 at 3 (citing *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1337-40 (Fed. Cir. 2015)).

and Avadel's infringement. While "[p]ast harm to a patentee's market share[] [and] revenues" is relevant to a finding of irreparable injury,[8] here, the magnitude of Jazz's past harm—and, more importantly, the likelihood that Avadel's infringement would continue to result in such harm—is uncertain given that at least some of the harm alleged by Jazz is attributable to generic competition. Considering the clear evidence of past harm in light of Jazz's attempts to dismiss the effects of generic competition, the Court finds that this factor, at most, weighs only slightly in favor of a permanent injunction. *See Advanced Cardiovascular*, 579 F. Supp. 2d at 560 (finding no irreparable harm where "[patentee] has not addressed the fact that [a third-party competitor] holds a larger market share than [defendant]").

2. *Inadequacy of Legal Remedy*

The second *eBay* factor "is nearly indistinguishable from irreparable injury" and asks whether legal remedies are adequate to compensate the patentee for the harm caused by the infringing conduct. *Natera*, 2023 WL 9103876, at *4. Avadel contends that this factor weighs against a permanent injunction because "Jazz has willingly licensed its Xyrem and Xywav patents to ten different direct competitors, for a zero percent royalty." D.I. 601 at 15. For the reasons discussed *supra*, the Court agrees that Jazz's willingness to forego its patent rights for compensation with generic manufacturers, despite the likely impact generic sales would have on Jazz's business, "supports [a] [] conclusion that [Jazz] will not suffer irreparable harm absent an injunction." *Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc.*, 579 F. Supp. 2d 554, 560 (D. Del. 2008), *dismissed*, 356 F. App'x 389 (Fed. Cir. 2009). However, Jazz's willingness to license to generic competitors "is but one factor for the [Court] to consider." *Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1328 (Fed. Cir. 2008) ("[T]he amount of weight

[8] *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 861 (Fed. Cir. 2010).

given to a patentee's prior willingness to grant licenses is solely within the discretion of the district court.").

Also relevant to the Court's analysis is the evidence of at least some past market share loss and price erosion, which typically "suggests that mere damages will not compensate for a competitor's increasing share of the market." *Douglas Dynamics, LLC v. Buyers Prod. Co.*, 717 F.3d 1336, 1345 (Fed. Cir. 2013); *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); *Natera*, 2023 WL 9103876, at *4 (Internal citations omitted) (finding that "'loss of market share, brand recognition, and customer goodwill,' . . . demonstrate inadequacy of monetary damages"). Having considered the record before it, the Court finds that legal remedies may be inadequate to compensate Jazz for the past irreparable harm caused by Avadel's infringement. This factor therefore weighs slightly in favor of an injunction.

3. *Balance of the Equities*

"To satisfy the third *eBay* factor, the patentee must show that the balance of hardships weighs in its favor." *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 645 (Fed. Cir. 2015) (citing *eBay*, 547 U.S. at 391). "This factor 'assesses the relative effect of granting or denying an injunction *on the parties*.'" *Id.* (quoting *i4i*, 598 F.3d at 862) (emphasis added). "As a preliminary matter, the balance considered is only between a plaintiff and a defendant, and thus the effect on customers and patients alleged by [the infringer] is irrelevant under this prong of the injunction test." *Acumed*, 551 F.3d at 1330. However, the Court may consider "the parties' sizes, products, and revenue sources." *i4i*, 598 F.3d at 862-63.

Here, Avadel maintains that the balance of hardship weighs against an injunction because Jazz "faces no existential risks in the absence of an injunction" while "[redacted]

[redacted]" D.I. 601 at 17. Jazz, in contrast, contends that its "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.'" D.I. 587 at 11-12. Jazz adds that Avadel "cannot escape an injunction simply because it is smaller than the patentee or because its primary product is an infringing one." *Id.* at 13 (citing *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1156 (Fed. Cir. 2011)). According to Jazz, Avadel's claims that an injunction would destroy its business are particularly inconsequential, considering the Federal Circuit's resolve that "[o]ne 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).

Yet, this is not a case where an infringer *elected* to build its business around an infringing product. *See Hynix Semiconductor Inc. v. Rambus Inc.*, 609 F. Supp. 2d 951, 970 (N.D. Cal. 2009) (distinguishing *Windsurfing* where the record proves that the infringement was not willful). Rather, Avadel's investment into Lumryz began in 2019, at a time when "claim 24 of the '782 patent ***did not exist***." D.I. 601 at 17 (emphasis in original); P.I. Tr. 83:20-84:7. While Jazz contends that Avadel "made a 'choice' to focus exclusively on Lumryz," this too was a decision made by Avadel in 2019, and Avadel maintains that it was wholly unaware of Jazz's intent to patent a similar treatment when the decision to prioritize Lumryz was made. Tr. 548:12-13. According to Avadel, when the'782 patent issued in October 2021, Avadel continued to have no knowledge of the patent, but "the design of Lumryz was locked in . . . [and] fully ready for FDA approval." D.I. 601 at 17. Thus, Avadel's alleged harm was not, as Jazz contends, "self-inflicted." D.I. 587 at 1. And "the potential destruction of [] [Avadel's] business

should carry some weight in the balancing of harms under the four-factor test reaffirmed in *eBay*." *See Hynix*, 609 F. Supp. 2d at 970; *see also Wonderland Switzerland AG v. Evenflo Co., Inc.*, No. 1:20-CV-00727-JPM, 2023 WL 4098571, at *7 (D. Del. June 7, 2023) ("[C]ourts may still consider hardships suffered by an infringer when determining whether an injunction is warranted.").

Considering the harm of an injunction to Avadel against the harm to Jazz of allowing Avadel's continued infringement, the Court finds that the balance tilts in Avadel's favor. Avadel is "a much smaller company" that "depends entirely on the sales of the enjoined products for its revenue." *Bio-Rad Lab'ys, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1379 (Fed. Cir. 2020); *but see Commonwealth Sci. & Indus. Rsch. Organisation v. Buffalo Tech. Inc.*, 492 F. Supp. 2d 600, 606 (E.D. Tex. 2007) (finding that hardship of injunction was not catastrophic where the infringing products made up "only eleven percent of [the infringer's] business"). Thus, even the limited injunction sought by Jazz could "[redacted]" Divis Decl., ¶ 6. And while Jazz will undoubtedly suffer harm from having to compete directly against an infringing product, "[Lumryz] is not a copycat product[] but was independently developed and provides important advantages over [Jazz's products] for patients." *Conceptus, Inc. v. Hologic, Inc.*, No. C 09-02280 WHA, 2012 WL 44064, at *3 (N.D. Cal. Jan. 9, 2012). Given this evidence and [redacted],[9] the Court finds that the balance of the equities weighs against an injunction.[10] *Id.* (finding that the

[9]D.I. 601 (explaining that, if an injunction is granted, "[redacted]").

[10]Jazz argues that the balance of the equities should not favor Avadel because "Avadel has purported to have invented other unit dosage forms that would *not* infringe Jazz's claim 24." D.I. 587 at 11. Jazz concedes, however, that "Avadel did not present any evidence of a non-infringing alternative to claim 24 at trial," and Jazz relies on disclosures in Avadel's patent that the "first principal structural embodiment" of Avadel's formulation does not include a viscosity

balance of hardships weighed against an injunction where the infringer "would have to lay off nearly three hundred employees who are directly related to the manufacture and research of [the infringing product] if an injunction is imposed").

4. *Public Interest*

More than any other *eBay* factor, the public interest strongly favors denying Jazz's request to enjoin Lumryz for narcolepsy. "The heart of the patent grant is the right to exclude. *See* 35 U.S.C. § 154(a)(1) ("Every patent shall contain ... a grant to the patentee ... of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States."). "Typically, in a patent infringement case, although there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of [injunctive] relief." *Hybritech Inc. v. Abbot Laboratories*, 849 F.3d 1446, 1458 (Fed.Cir.1998); *Wesley Jessen Corp. v. Bausch & Lomb, Inc.*, 209 F. Supp. 2d 348, 404 (D. Del. 2002), *aff'd*, 56 F. App'x 503 (Fed. Cir. 2003) ("In patent cases, courts only exercise their discretion to deny injunctive relief when the harm to the public from granting the injunction is so severe that it outweighs the patentee's individual right to exclude."); *Amgen, Inc. v. Sanofi*, 872 F.3d 1367, 1381 (Fed. Cir. 2017) (holding that where a "plaintiff fails to show 'that the public interest would not be disserved by a permanent injunction,' then the district court may not issue an injunction"). Particularly, "[i]n litigation such as this involving a medical product, the public

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enhancing agent or an acid. *Id.* (noting that Avadel's witness confirmed during trial that "everything in [the '062 Patent] to be true and accurate."). This evidence, however, does not persuade the Court that Avadel had a "new design around [that] was ready for implementation" and does not defeat Avadel's claim that the balance of the harm weighs in its favor. *See Douglas*, 717 F.3d at1345 ("If indeed [defendant] had a non-infringing alternative *which it could easily deliver to the market*, then the balance of hardships would suggest that Buyers should halt infringement and pursue a lawful course of market conduct." (emphasis added)).

has 'two primary interests'—i.e., the 'protection of intellectual-property rights and access to necessary and effective medical care.'" *Abbott*, 2019 WL 2521305, at *25 (quoting *Baxalta*, 2018 WL 3742610, at *12). Thus, courts have denied motions for injunctions "when doing so would eliminate 'an important alternative for patients.'" *Id.* (quoting citation omitted); *see also Custom Designs of Nashville, Inc. v. Alsa Corp.*, 727 F. Supp. 2d 719, 727 (M.D. Tenn. 2010) ("A number of cases indicate that the denial of an injunction for reasons of public interest is limited to cases where public health or safety are threatened, but that in general, the benefits derived from protecting a person's patent sufficiently serve the public interest.").

Avadel contends that a permanent injunction would harm the public interest by removing from the market a treatment for narcolepsy that offers "unique medical benefits" otherwise not offered by Xyrem and Xywav. D.I. 601 at 3. Specifically, Avadel argues that Lumryz constitutes an important alternative for patients with narcolepsy by offering those patients the only single-dose treatment regimen in the market. *Id.* at 4. Xyrem and Xywav, on the other hand, require patients with narcolepsy "to take one dose of oxybate at bedtime and a second dose two and a half to four hours later." Tr. 635:14-22. Avadel's expert, Dr. Corser, testified during trial that Xyrem and Xywav "ha[ve] not been appealing, either for doctors or for patients" because the twice-nightly treatment regimen means that patients must wake up to take the second dose. *Id.* at 635:14-22. Conversely, because Lumryz is only taken once before bedtime, Lumryz "giv[es] narcolepsy patients—for the first time—the chance to get an undisturbed night's sleep." D.I. 601 at 3.

To counter Avadel's argument that Lumryz is the superior treatment, Jazz cites "data show[ing] that both parties' products similarly reduce the number of narcolepsy nighttime awakenings from about 80 to about 40." D.I. 610 at 1; Jazz Exs. 20-22. Yet the data cited by

Jazz does not refute Avadel's claim that Lumryz gives patients with narcolepsy "a better chance to get undisturbed sleep than Jazz's products," as the basis for Avadel's claim is not that Lumryz is more *effective* in *treating* or *preventing* symptoms of narcolepsy. Rather, Avadel argues that, unlike Xywav and Xyrem, Lumryz offers a unique benefit to patients *by eliminating the requirement* that patients take a second late-night dose. D.I. 601 at 4. Accordingly, Avadel claims that an injunction would harm the public interest by preventing patients with narcolepsy from accessing a treatment that is easier to administer. Stern Decl., ¶¶ 6-8

Notably, the FDA similarly found that Lumryz 's single dose regimen treatment made it clinically superior "to every previously approved oxybate drug . . . , [including] both Xywav and Xyrem," for patients with narcolepsy. Avadel Ex. 1 at JTX-112.3. The FDA's determination relied on the opinions of "agency sleep experts" who agreed that "disrupting sleep contributes to chronic sleep loss[] [and] is well known to cause reduced performance, increased risk for accidents and death, and detrimental effects on both psychological and physical health." *Id.* at JTX-0112.3, JTX-112.33. Thus, the FDA found that a treatment for narcolepsy that required patients "to wake up to take a second dose" would be "antithetical to [the treatment's] goal of improving sleep" because it would force a nocturnal arousal on patients who already struggle to get sufficient night-time sleep. *Id.* at JTX-112.29. Because Lumryz eliminated the need for patients with narcolepsy to wake up for the second dose, the FDA concluded that Lumryz was "inherently more convenient, easier, and less burdensome," and thus was the superior treatment for narcolepsy.[11] *Id.* at JTX-112.30.

[11]Jazz contends that "[t]he FDA found that Xywav's significantly lower amount of sodium is 'safer' for 'all patients with narcolepsy.'" D.I. 587 at 9. Jazz, however, mischaracterizes the FDA's findings, which were "not based on Lumryz providing greater safety than Xyrem and Xywav" and did "not respond[] to each safety argument from Jazz." Avadel Ex. 1 at JTX-

Jazz contends that "the FDA made clear that its finding was not based on better safety or efficacy." D.I. 587 at 15. While the Court agrees that the FDA did not determine whether Lumryz was a safer or more effective treatment for narcolepsy, Avadel can show that its infringing product constitutes an important alternative for patients even in the absence of such evidence. *Baxalta* is illustrative. 2018 WL 3742610. There, the district court found that a Breakthrough Therapy designation by the FDA "indicate[d] that the [infringing] drug may demonstrate a substantial improvement over existing therapies" where the patentee sought to enjoin the sale and production of an infringing drug used to treat hemophilia. *Id.* at *3. In denying injunctive relief, the *Baxalta* court noted that the infringing drug was administered through "a once-weekly subcutaneous injection" while the patented treatment required administration by infusion "at least two times a week." *Id.* Identifying this difference in the administration requirements of each treatment, the *Baxalta* court held that the infringing product "represent[ed] a potential sea change in the treatment of [] hemophilia" because it offered patients an option for "prophylactic therapy with *a significantly lower treatment burden*." *Id.* at

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0112.34. Acknowledging "that the sodium content of Lumryz raises [] [some] safety concern[s]," particularly for patients with sensitivity to sodium, the FDA determined that, with respect to both patients with sodium restrictions and patients who are not sensitive to sodium, "the benefit offered by once-nightly dosing would [still] outweigh the risk of increased sodium intake." *Id.* at JTX-0112.33; *id.* at JTX-0112.34 (noting that the FDA "acknowledged [] that Lumryz has a higher sodium content than Xywav and addressed why Lumryz is still clinically superior to Xywav"). Thus, the Court does not read the FDA's superiority determination as applying only to patients with no salt-sensitivity. *Compare* D.I. 587 at 16 (claiming that the FDA's "clinical superiority finding was not for 'the entire patient population for which [Lumryz] is intended'") *with* Avadel Ex. 1 at JTX-0112.32 ("[W]e believe that the benefit of Lumryz's once-nightly dosing outweighs the safety concern raised by its increased sodium content for a substantial number of narcolepsy patients.") *and* Avadel Ex. 1 at JTX-0112.33 ("For certain sodium-sensitive patients with narcolepsy, the benefit offered by once-nightly dosing would outweigh the risk of increased sodium intake . . . .").

*13 (emphasis added). Thus, "the public interest favor[ed] availability of [this less burdensome] treatment." *Id.*

Similarly, in this matter, the FDA's superiority determination strongly indicates that the public interest favors the availability of Lumryz for narcolepsy. As with the infringing treatment in *Baxalta*, Lumryz's single-dose treatment regimen benefits patients with narcolepsy by eliminating the need to "wak[e] up to take medication during the night after falling asleep[]." Avadel Ex. 1 at JTX-0112.12. The FDA explained that this benefit can be crucial for patients with narcolepsy, since "even [] a single nocturnal arousal[] [] can [cause] impairment of alertness and decline in cognitive performance the following day." *See id.* at JTX-01112.29 ("Awakening to take a second dose necessarily disrupts sleep and causes fragmented sleep. A person with disrupted sleep cannot simply return to sleep and resume their normal sleep cycle. . . . So, upon taking a second dose of Xyrem or Xywav, after the minimum of 5-15 minutes to return to sleep, such sleep does not resume where the patient left off to take their medication."). A single-dose treatment regimen, on the other hand, aligns more effectively with the goal of narcolepsy treatment (i.e., "maximize the time in sleep and minimize wake time") by eliminating the need to wake mid-sleep for a second dose. *Id.* Such a treatment also reduces the burden on patients of having to arrange for such a late-night dose. *Id.*; Stern Decl., ¶¶ 7-8 (noting "[t]hat patients taking Xyrem or Xywav must set an alarm to take the second dose in the middle of the night" makes compliance less likely, as "patients [] struggle[] to adhere to the dosing regimen"); Lavender Decl., ¶ 12 ("[I]t is not some minor issue that people do not want to have to set an alarm in the middle of the night. Neither Xyrem nor Xywav is an easy treatment. The treatment upends your life."). Thus, Avadel has proven that Lumryz represents a "sea change" in the treatment of narcolepsy by offering patients a less burdensome treatment option.

In light of this evidence, the public interest weighs notably against even the "limited" injunction sought by Jazz. Lumryz is the only single-dose treatment for narcolepsy, and the FDA's superiority determination recognized that Lumryz is "significantly more convenient for patients" and "an advancement in the ease of drug administration." Avadel Ex. 1 at JTX-01112.29. Avadel offered first-hand accounts from patients and providers noting their preference for Lumryz's once-nightly treatment regimen over Jazz's two-dose oxybate treatments. *See, e.g.*, Lavender Decl., ¶¶ 12-17; Patient 1 Decl., ¶¶ 6-11; Patient 2 Decl., ¶¶ 6-10. While Jazz contends that a limited injunction reduces the likelihood of public harm by ensuring that no existing Lumryz patients are enjoined from continuing their use of Lumryz, Jazz seeks an injunction that "would make Lumryz unavailable 'to the vast majority of [narcolepsy] patients in need of [Lumryz] treatment.'" D.I. 601 at 10 (citing *Baxalta*, 2018 WL 3742610, at *13). In doing so, Jazz ignores that patients with narcolepsy who have not been prescribed Lumryz would also "continue to benefit[] from having a choice of products."[12] *Conceptus*, 2012 WL 44064, at *3-*4; *see also Baxalta*, 2018 WL 3742610, at *12 (explaining that the public interest disfavored enjoining a treatment that "differ[s] in meaningful ways" from other existing products on the market). In fact, there are "multiple reasons patients may want to take Lumryz in the future but are not taking it yet." Stern Decl., ¶ 21. As Avadel's expert Dr. Thomas Stern explained:

[12]The Court recognizes that some patients may benefit more from Xywav given its reduced sodium content. However, the FDA found "that the benefit of Lumryz's one-nightly dosing outweighs the safety concern raised by its increased sodium content for a substantial number of narcolepsy market." Avadel Ex. 1 at JTX-0112.32. While Jazz disagrees and notes that has initiated proceedings to challenge the FDA's determination on this ground, the public interest that the Court seeks to protect is the interest in patient choice, and the Court's decision ensures that all patients seeking narcolepsy treatment have the option to take a treatment that offers unique and substantial benefits. The law does not require the Court to find that Lumryz *is* the best treatment option for all patients with narcolepsy.

> Some [patients] have not yet been diagnosed with narcolepsy. Others have been diagnosed with narcolepsy and would benefit from Lumryz but have not started taking it because they have not had a follow-up visit recently or have not yet gone through the somewhat cumbersome process of enrolling in the FDA-mandated risk evaluation and mitigation system (REMS) for Lumryz or securing coverage from their health insurer. Some are not yet 18 years of age. *Id.*

Jazz responds that these patients can be treated with Jazz's oxybate products. *See* D.I. 597 at 14 (citing JTX87.3) (noting "that Lumryz's labeling instructs that Jazz's patients are to switch to 'the nearest equivalent [Lumryz] dosage in grams per night.'"). Yet, Jazz does not offer a once-nightly treatment for narcolepsy, and the record does not indicate that Jazz intends to offer a once-nightly narcolepsy treatment "for commercial sale very soon." *Edwards Lifesciences AG v. CoreValve, Inc.*, No. CV 08-91 (GMS), 2014 WL 1493187 (D. Del. Apr. 15, 2014) (excluding from an injunction those patients who "cannot be helped" by the patentee's products). Thus, with respect to their administration requirements, Jazz's oxybate treatments and Lumryz "are 'not interchangeable products." *Abbott*, 2019 WL 2521305, at *27 (internal citations omitted). Given the detrimental effects of sleep deprivation and sleep fragmentation for patients with narcolepsy, it is in the public's interest to have continued access to the less burdensome treatment. Avadel Ex. 1 at JTX-01112.13. Moreover, this interest in protecting patient access to the only once-nightly narcolepsy treatment in the narcolepsy market "'militates strongly against an injunction.'" *Abbott*, 2019 WL 2521305, at *26-*27 (internal citations omitted); *Conceptus*, 2012 WL 44064, at *4 (N.D. Cal. Jan. 9, 2012).

In sum, having considered each of the *eBay* factors, the Court finds the threat to Avadel's business and, more importantly, the substantial harm to the public interest that would result from an injunction outweigh any irreparable injury suffered by Jazz in the absence of such injunctive relief. Accordingly, Jazz's request for a permanent injunction barring the prescription of Lumryz for the treatment of narcolepsy is **DENIED**.

B. *The eBay factors weigh in favor of enjoining Avadel from seeking FDA approval and marketing Lumryz for IH.*

1. *Irreparable Harm*

According to Jazz, Lumryz's entrance into the market for IH would irreversibly harm Jazz's market share and damage its ability to build its reputation as the exclusive market leader. D.I. 587 at 4-5, 7-8. For the following reasons, the Court agrees that Jazz would suffer irreparable injury if Avadel is not enjoined from seeking FDA approval and marketing Lumryz for IH.

Unlike the narcolepsy market where Jazz's products compete with several other oxybate therapies, Jazz's Xywav is the only FDA-approved treatment for IH. Tr. 92:17-21, 520:5-8. While Avadel does not currently manufacture or sell competing products in the IH market, Avadel does not dispute that it is pursuing FDA approval of Lumryz for the treatment of IH. Tr. 519:17-19. The evidence shows that Avadel's interest in the IH market stems from its recognition that the market holds "a lot of opportunity" because "there's a robust patient population . . . with only one currently FDA approved treatment, [Xywav]." Jazz Ex. 2 at 23. Because Xywav is the only FDA approved treatment for IH, Lumryz's entrance into the IH market would undoubtedly cause Jazz to suffer significant injury.

Indeed, with FDA approval, Lumryz will compete head-to-head against Xywav in a newly-developing market. *Douglas,* 717 F.3d at 1345 ("Where two companies are in competition against one another, the patentee suffers the harm—often irreparable—of being forced to compete against products that incorporate and infringe its own patented inventions."). Avadel responds that Jazz's complaints about "losing its first-mover advantage are overstated." D.I. 601 at 4 (internal citations omitted). Yet, evidence shows that, since acquiring FDA approval to market Xywav for IH in August 2021, Jazz has seen dramatic increases in the

number of IH patients taking Xywav year-to-year. P.I. Tr. 16:7-10, 17:12-19 (noting a 59% growth of Xywav for IH in 2023). Additionally, as recently as March 2024, Avadel's CEO admitted that Avadel "watched [Xywav] advance" over the two years since their launch in the IH market and noted "a lot of opportunity remained" because Jazz showed less than a ten percent market penetration. Jazz Ex. 2 at 23:10-21.

Given this evidence, the Court agrees 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." *Illumina, Inc. v. Qiagen, N.V.*, 207 F. Supp. 3d 1081, 1093 (N.D. Cal. 2016). "[A]s the first entrant into the marketplace, [Avadel] would have advantages that include working with the best facilities and potential customers and being perceived as an innovator in the field." *See Butamax Advanced Biofuels LLC v. Gevo, Inc.*, 868 F. Supp. 2d 359, 375 (D. Del.), *remanded-in-part on other grounds. Butamax(TM) Advanced Biofuels LLC v. Gevo, Inc.*, 486 F. App'x 883 (Fed. Cir. 2012); *see also Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (finding irreparable harm where "price erosion and loss of market position was likely").

Moreover, Xywav's title as the only FDA-approved treatment for IH "is an intangible asset that is part of a company's reputation . . . ." *Douglas*, 717 F.3d at 1345. Because Jazz intends to use its exclusivity in the IH market to brand itself as the market leader, Avadel's entrance into the market would strip Jazz of a unique selling point critical to growing its reputation and goodwill. *See id.* at 1344 (recognizing that a patented product may "lose some of its distinctiveness and market lure because competitors could contend that they had 'similar features' without noting that those features infringe"). Thus, Jazz would also suffer reputational harm from "being precluded from marketing to potential and existing customers that it is the

exclusive market leader." *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930-31 (Fed. Cir. 2012). This reputational harm and the accompanying market share loss caused by Avadel's direct competition would likely be irreparable. *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc.*, 821 F. Supp. 2d 681, 694 (D.N.J. 2011), *aff'd and remanded sub nom. Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc., USA*, 748 F.3d 1354 (Fed. Cir. 2014) (finding irreparable harm where "[p]laintiffs and [d]efendants are two head -to-head competitors in the [relevant] marketplace; every sale of [d]efendants' generic [product] is a lost sale by Plaintiff"). Accordingly, this factor weighs in favor of a permanent injunction.[13]

2. *Inadequacy of Legal Remedies*

Additionally, Jazz has satisfied its burden of showing that monetary remedies would not adequately compensate the harm caused by Lumryz's introduction into the market for IH. This factor can be met by evidence of "loss of market share, brand recognition, and customer goodwill . . . particularly when the infringing acts significantly change the relevant market." *i4i*, 598 F.3d at 862. Here, the approval of Lumryz for IH would significantly change the market by allowing a second treatment to compete directly with Jazz's Xywav. *See Novozymes A/S v. Genencor Int'l, Inc.*, 474 F. Supp. 2d 592, 613 (D. Del. 2007) (finding legal remedies inadequate because patentee and infringer "are head-to-head competitors, and [patentee] has a right, granted by Congress, not to assist its rival with the use of proprietary technology"). Also, as the Court noted *supra*, Jazz's exclusivity in the IH market is itself an intangible asset, and Jazz will likely suffer reputational harm that cannot be compensated by legal remedies. *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1340 (Fed. Cir. 2012) ("Loss of business

[13]For the same reasons noted with respect to Jazz's request to enjoin Lumryz for narcolepsy, Jazz has shown a sufficient nexus between the irreparable harm asserted by Jazz and Avadel's continued infringement. *See supra* at 8-10.

opportunity or damage to brand recognition could provide a basis for concluding that monetary relief would be inadequate.").

3. *Balance of the Equities*

The balance of the equities also tips in Jazz's favor. While the Court is persuaded that enjoining Lumryz for narcolepsy would irrevocably harm Avadel's business, Avadel cannot allege the same injury with respect to the IH market, where Avadel still lacks FDA approval to sell Lumryz. And while Avadel notes that it "intends to invest $30-40 million" in clinical trials evaluating the contributions of Lumryz in treating IH, Avadel concedes that it "has not yet started [any] clinical trial[s]" and would not do so if an injunction was granted. *See* P.I. Tr. 64:15-21, 86:1-8 (explaining that the trials would not occur "if there was no way that it could sell the product at the conclusion of that clinical trial."). Thus, enjoining Lumryz for IH would not spell "the end of Avadel." *See* D.I. 601 at 17.

"On the other hand, requiring [Jazz] to compete against its own patented invention . . . places a substantial hardship on [Jazz]," particularly given that Lumryz would be the only other FDA-approved treatment for IH. *Robert Bosch*, 659 F.3d at 1156; *see also* Jazz Ex. 2 at 23 (Avadel's CEO recognizing "a lot of opportunity" in the IH market). Jazz contends that it is working to grow its position and reputation in the IH market and, as the Court noted above, Jazz has a pointed interest in protecting its market exclusivity. This factor therefore weighs in favor of a permanent injunction.

4. *Public Interest*

Avadel contends that the same public interest considerations that counsel against enjoining Lumryz for narcolepsy are relevant to Jazz's request to enjoin Lumryz for IH. D.I. 601

at 9-10. For the following reasons, the Court disagrees and finds that the public interest weighs in favor of enjoining Lumryz in the IH market.

According to Avadel, "IH is best thought of as being on a spectrum with narcolepsy," as "[p]atients with either condition suffer from excessive daytime sleepiness," "[d]iagnostic criteria are similar and imprecise," and "oxybate is a very effective treatment for IH." *Id.* at 9. While the Court agrees that both narcolepsy and IH are sleep-related disorders that share many common symptoms, the weight of the evidence indicates that the conditions are distinguishable. Jazz's expert witness, Dr. Richard K. Bogan, explained that "Narcolepsy and IH are two unique chronic sleep disorders with the common symptom of excessive daytime sleepiness ('EDS')." Bogan Decl., ¶ 10. While both conditions cause patients to suffer EDS, "IH patients[] [] present other symptoms that are typically distinct from narcolepsy." *Id.*, ¶ 14. These symptoms include "sleep inertia where the patient experiences difficulty waking from a long sleep, unrefreshing naps, and long sleep times of 11 or more hours per 24-hour period." *Id.*

Avadel's expert, on the other hand, alleged that IH was particularly similar in "presentation and diagnostic criteria to [Narcolepsy Type 2]," making the two conditions "difficult to distinguish." Stern Decl., ¶ 14. While Dr. Bogan agreed that IH and narcolepsy Type 2 have many "overlapping symptoms," he explained that Type 2 tends to cause patients to suffer from fragmented sleep. Bogan Decl., ¶ 12. Patients with IH, on the other hand, "typically have longer sleep times." *Id.* Thus, Dr. Bogan testified that practitioners can distinguish between the two conditions. *Id.* Dr. Bogan supported his opinions with several peer-review papers "consistently characterize[ing] IH and narcolepsy [] as distinct diseases." *Id.* at Ex. C, Dauvilliers 2022 at 7 (explaining that IH "may coexist with other disorders. . . but is incompatible with others, such as narcolepsy"); Ex. D, Landzberg, D and Trotti, L.M., *Is*

Idiopathic Hypersomnia a Circadian Rhythm Disorder?, Curr. Sleep. Med. Rep. 5(4):201-206 (2019) ("IH is diagnosed based on clinical history in combination with objective quantification of excessive daytime somnolence . . . after excluding other causes of sleepiness such as narcolepsy type 1 [and] narcolepsy type 2"). Several of these papers distinguished IH "from narcolepsy on the basis of the presence of prolonged rather than short diurnal sleep periods . . . ." *Id.* at Ex. E, Bruck, D. and Parkes, J.D., *A comparison of idiopathic hypersomnia and narcolepsy-cataplexy using self report measures and sleep diary data*, JNNP 60:576-578 (1996); Ex. F, Manfredi, R.L., et al., *Disorders of excessive sleepiness: narcolepsy and hypersomnia*, Semin. Neurol. 7(3):250-58 (1987) ("Nocturnal sleep is typically disrupted in narcolepsy, whereas in idiopathic hypersomnia it is prolonged."). During a conference presentation in March 2024, Avadel's CEO similarly recognized that IH is "different from narcolepsy in that [IH patients] really physically struggle at times with waking up with the deep sleep inertia that they suffer from." Jazz Ex. 2 at 23:10-24:1.

The separate FDA-labeled-indications for IH and narcolepsy also support the Court's finding that the two conditions are distinct. For instance, Xywav is FDA-approved for once nightly administration to treat IH and must be administered in two doses to treat narcolepsy. Citing only to the declaration of its expert, Dr. Stern, however, Avadel argues that the Court should disregard the FDA's approval of once nightly Xywav to treat IH because a "vast majority of IH patients take [Xywav] twice nightly." D.I. 601 at 8 (citing Stern Decl., ¶ 16). Yet, Avadel provided no evidence to substantiate Dr. Stern's claim. *See* Stern Decl., ¶ 16 (noting only that, "in [his] own practice, [Dr. Stern] always starts patients on twice-nightly oxybate for IH"). Jazz, on the other hand, cited clinical research finding no substantial difference between once nightly dosing and twice nightly dosing of Xywav for IH treatment. *See* Jazz Ex. 26 at 63. When

viewed as a whole, the weight of the evidence shows that IH and narcolepsy are distinct conditions and that Xywav can—and very likely is—administered in a single dose to treat the symptoms of IH.

Given these distinctions between the two conditions, Avadel cannot rely on the FDA's determination that "Lumryz is clinically superior to Xywav" to support its claim that the public interest weighs against the injunction of Lumryz for IH. Indeed, the FDA's superiority determination extends only to the narcolepsy market. Avadel responds that the Court's decision to enjoin Lumryz for IH should not turn on its lack of FDA approval because "[t]he key public-interest consideration is whether an injunction would cut off patient access to a differentiated product that offers a 'unique' medical benefit, not whether there has been a clinical superiority determination." D.I. 601 at 9. While the Court agrees that the public interest may disfavor an injunction even in the absence of an FDA superiority finding, in this case, the FDA's ODE determination was crucial to the Court's finding that Lumryz offered a "unique" medical benefit to patients with narcolepsy. *See supra* at 15-21. In opposing an injunction of Lumryz™ for narcolepsy, Avadel argued consistently with the FDA that Lumryz was the superior treatment because it eliminated the need for narcolepsy patients to wake for a late-night second dose. *See* D.I. 609 at 4-5. After reviewing the FDA's ODE determination and the evidence before it, the Court agreed that the public had a significant interest in accessing the only single-dose treatment for narcolepsy. *See supra* at 15-21. Given the FDA's approval of once-nightly Xywav as a safe and effective treatment for IH, however, the Court is not persuaded that Lumryz offers IH patients the same "unique" benefit. As Avadel has not shown that Lumryz offers any other distinct benefits to patients with IH, the Court cannot find that enjoining Lumryz for IH would harm the public interest by "cutting off" access to a differentiated product.

Ultimately, to show that the public interest weighed against an injunction, Avadel had the burden to prove that enjoining Lumryz for IH would result in a harm to the public that outweighs the public's competing interest in incentivizing "innovative drug companies to continue costly development efforts." *Sanofi-Synthelabo*, 470 F.3d at 1383 (finding that the "'public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents' tips the scale in [the patentee's] favor"). Yet, Avadel failed to show that Lumryz is a superior or unique treatment for IH. Avadel's claim that "[p]hysicians have [] urged Avadel to seek FDA approval for Lumryz in IH" is similarly insufficient to outweigh the public's interest in enforcing patent rights and encouraging innovation. *See* D.I. 601 at 8. Accordingly, this factor weighs in favor of enjoining Lumryz for IH.

5. *Unclean Hands*

Avadel contends that Jazz cannot obtain equitable relief because of Jazz's attempts to use "unlawful and improper means" to block Avadel's participation in the marketplace. D.I. 601 at 18. Federal Rule of Civil Procedure 8(c), however, requires the affirmative defense of unclean hands to be pled affirmatively, and "[f]ailure 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). Because Avadel failed to plead unclean hands, that defense is waived. D.I. 610 at 5. Moreover, the defense would not succeed even if properly pled by Avadel given that "the primary principle guiding application of the unclean hands doctrine is that the alleged inequitable conduct must be connected, *i.e.,* have a relationship, to the matters before the court for resolution." *In Re New Valley Corp.,* 181 F.3d 517, 525 (3d Cir.1999) (internal citations omitted). "In the context of patent litigation, assertions of unclean hands have typically succeeded only in situations in which the misconduct related in some way to the

procurement of the particular patent in question." *In re Gabapentin Pat. Litig.*, 648 F. Supp. 2d 641, 650 (D.N.J. 2009). Jazz's exclusion of Avadel from the marketplace does not directly relate to Jazz's claim asserting its patent rights. Accordingly, the defense, even if properly pled, would not bar Jazz from seeking an injunction.

Because the *eBay* factors counsel in favor of an injunction, Jazz's request to enjoin Avadel from pursuing FDA approval for Lumryz to treat IH and from marketing Lumryz for IH treatment is **GRANTED**.

2. Ongoing Royalties

A. *Jazz is entitled to ongoing royalties for sales of Lumryz for narcolepsy.*

"If the court determines that a conduct-barring injunction is not warranted, it may instruct the parties to try to negotiate an ongoing royalty and, if the parties cannot agree, award a royalty." *Prism Techs. LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360, 1377 (Fed. Cir. 2017). While the jury awarded Jazz a 3.5% royalty rate for past damages, Jazz argues that the awarded royalty should be increased to an ongoing rate of "27% through 2025, 13% from 2026 through 2032, and 3.5% from 2033 through February 2036." D.I. 587 at 17-18. Avadel, on the other hand, requests that the Court "view the jury award as a fully-paid-up royalty" or, alternatively, "treat the award as a determination that Avadel should pay a 3.5% royalty on 20% of Avadel sales." D.I. 601 at 19.

Although the Court recognizes that the award of an ongoing royalty is not automatic, the Court agrees with Jazz that an award of royalties is warranted to remedy the future sales of Lumryz for narcolepsy. The decision to award such a royalty is solely within the Court's discretion. *See Paice LLC v. Toyota Motor Corp.,* 504 F.3d 1293, 1315 (Fed.Cir.2007). Moreover, "the Federal Circuit has indicated that a prevailing patentee should receive

compensation for any continuing infringement." *Apple, Inc. v. Samsung Elecs. Co.*, No. 12-00630-LHK, 2014 WL 6687122, at *7 (N.D. Cal. Nov. 25, 2014) (citing *Telcordia Techs., Inc. v. Cisco Sys., Inc.*, 612 F.3d 1365, 1379 (Fed.Cir.2010)). Here, the record clearly establishes that Avadel intends to offer and sell a wholly infringing product to treat narcolepsy. The evidence also shows that Avadel recognizes that its product will compete directly with Jazz's oxybate products for market share and other market opportunities. As some evidence indicates that Avadel has and continues to target patients currently being treated by Xyrem or Xywav (i.e., so-called "switch-patients"), the Court agrees that an ongoing royalty award is necessary to compensate for Avadel's continuing infringement of the '782 patent. Avadel's motion for ongoing royalties is therefore granted.

B. *Additional testimony is necessary to determine the proper rate.*

In determining the appropriate ongoing royalty rate, the Court must consider: (1) change in bargaining position; (2) changed economic circumstances; and (3) any post-verdict factors affecting a post-verdict hypothetical negotiation. *See Vectura Ltd. v. GlaxoSmithKline LLC*, No. CV 16-638-RGA, 2019 WL 4346502, at *7 (D. Del. Sept. 12, 2019). "Generally, the jury's damages award is a starting point for evaluating ongoing royalties." *Apple, Inc.*, 2014 WL 6687122, at *14. Courts have increased the jury's royalty rate for ongoing infringement where "there was evidence of changed economic circumstances, in addition to the patentee being in a stronger bargaining position." *Purewick Corp. v. Sage Prod., LLC*, 666 F. Supp. 3d 419, 449 (D. Del. 2023), *appeal dismissed*, No. 2023-1868, 2023 WL 4230367 (Fed. Cir. June 28, 2023), *and appeal dismissed*, No. 2024-1184, 2024 WL 889332 (Fed. Cir. Mar. 1, 2024).

Here, given Jazz's status as the prevailing party, the Court agrees that Jazz is in a stronger bargaining position. *Amado v. Microsoft Corp.*, 517 F.3d 1353, 1361 (Fed.Cir.2008) ("There is a

fundamental difference [] between a reasonable royalty for pre-verdict infringement and damages for post-verdict infringement.") (internal citations omitted).[14] Yet, the parties submitted limited briefing on any economic factors or post-verdict factors for the Court to consider in determining the appropriate ongoing rate. Also, given that Jazz was the only party to present testimony from a damages expert during trial, the Court finds that additional briefing and evidence is necessary to determine the extent to which Jazz's bargaining position and changes in the economic circumstances justify an increase in the rate awarded by the jury.[15] Accordingly, while the Court agrees that Jazz may be entitled to ongoing royalties at a rate greater than the 3.5% rate awarded by the jury, the Court will reserve judgment on the appropriate ongoing royalty rate to compensate Jazz for Avadel's future infringement in the narcolepsy market, pending additional briefing from the parties.

III. CONCLUSION

For the foregoing reasons, the Court **GRANTS-IN-PART** and **DENIES-IN-PART** Plaintiffs Jazz Pharmaceuticals Inc. and Jazz Pharmaceuticals Ireland Limited's Motion for a Permanent Injunction and for an Ongoing Royalty (D.I. 586). An appropriate Order will follow.

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[14]Indeed, "[p]rior 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,* 517 F.3d at 1362. Accordingly, "[a]n assessment of prospective damages for ongoing infringement should 'take into account the change in the parties' bargaining positions, and the resulting change in economic circumstances, resulting from the determination of liability.'" *ActiveVideo*, 694 F.3d at 1343 (internal citations omitted).

[15]In deciding the royalty rate for post-trial infringement, the Court may consider "any new evidence that was not before the jury and additionally any changed circumstances (other than willfulness) between a hypothetical negotiation that occurred . . . (which the jury determined) and a hypothetical negotiation that would occur [now] after the judgment." *Mondis Tech. Ltd. v. Chimei InnoLux Corp.*, 822 F. Supp. 2d 639, 647 (E.D. Tex. 2011), *aff'd sub nom. Mondis Tech. Ltd. v. Innolux Corp.*, 530 Fed.Appx. 959 (Fed. Cir. 2013).