







IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,)
) C.A. No. 21-691 (GBW)
 Plaintiff,)
) 
 v.) 
)
 AVADEL CNS PHARMACEUTICALS LLC,)
) **PUBLIC VERSION**
 Defendant.)

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

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

JAZZ’S RESPONSIVE LETTER BRIEF IN SUPPORT OF ONGOING ROYALTY

Dear Judge Williams:

Jazz submits this response to Avadel’s submissions (D.I. 690 (“Br.”), D.I. 691 (“Rao”)) regarding the appropriate ongoing royalty for Avadel’s continuing infringement of claim 24.¹ As discussed below, Avadel’s request that the Court limit the ongoing royalty to 3.5% (the jury’s rate for past infringement) or “at most, 4.2%” is not grounded in the law or specific facts of this case. Avadel fails to give due weight to the parties’ changed bargaining positions, relies on a flawed analysis of post-verdict *Georgia-Pacific* (“GP”) factor nos. 3, 5, and 8-10, and fails to even consider post-verdict GP factor nos. 1, 4, 11, and 13, all of which support Jazz’s proposed rates of 30% through 2025, 13% from 2026 through 2032, and 3.5% (the jury’s rate) from 2033 through the ’782 patent’s expiration based on Lumryz sales for narcolepsy. A proposed order is attached.

I. Avadel Does Not Properly Account For Jazz’s Stronger Bargaining Position

Avadel fails to give proper weight to this Court’s finding that “Jazz is in a stronger bargaining position” post-verdict. D.I. 665 at 31. In an attempt to overcome this finding, Avadel ignores controlling Federal Circuit law that “there has been a substantial shift in the bargaining position of the parties” when a defendant “has been adjudicated to infringe and the patent has been held not invalid after a substantial challenge.” *ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1342 (Fed. Cir. 2012); *see also 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.”); *Telcordia Techs., Inc. v. Cisco Sys., Inc.*, No. 04-876, 2014 WL 1457797, at *4 (D. Del. Apr. 14, 2014) (“For that reason, courts frequently impose a post-verdict ongoing rate that is higher....”). Here, Avadel stipulated to infringement and mounted what it surely considers to have been a “substantial challenge” to the validity of claim 24. *ActiveVideo*, 694 F.3d at 1342; Br. at 4 (“[J]ury deliberations were lengthy.”).

Avadel also disregards its weaker position at the post-verdict hypothetical negotiation. Not only is Avadel an adjudicated infringer of a valid patent, but Lumryz remains Avadel’s only commercial product (with no new products on the horizon), Avadel has not attempted to design-around claim 24, its continued infringement is voluntary and intentional, and without a hypothetical license to continue selling Lumryz, it risks substantial additional damages if a second jury were asked to decide a royalty on post-verdict sales. D.I. 687 at 2-3; D.I. 688 (“Little Decl.”) at ¶¶11-25; Rainey Decl. ¶¶14, 46, 49, 55-59, 72-73; Rainey R. Decl. ¶¶8, 38, 41, 44; *see also Paice LLC v. Toyota Motor Corp.* (“*Paice III*”), 609 F. Supp. 2d 620, 626 (E.D. Tex. 2009) (“[C]ontinued infringement is willful and [] a new lawsuit ... would likely result in treble damages and could potentially be considered an exceptional case.”); *cf. VirnetX v. Apple Inc.*, 324 F. Supp. 3d 836, 861 (E.D. Tex. 2017) (continuing infringement after a jury verdict is willful and “unreasonably risky or reckless”).

“[F]ailure to consider the parties’ changed legal status would create an incentive for every defendant to fight each patent infringement case to the bitter end because without consideration of the changed legal status, there is essentially no downside to losing.” *Telcordia*, 2014 WL 1457797, at *4 (citing *Paice III*, 609 F. Supp. 2d at 628); *see also Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, No. 14-62369, 2017 WL 7732873, at *3 (S.D. Fla. Jan. 3, 2017) (“The purpose of an ongoing royalty is precisely to reduce the incentive to infringe.”), *aff’d*, 876 F.3d 1350 (Fed. Cir.

¹ Jazz also relies on the Responsive Declaration of Mark Rainey, Ph.D. (“Rainey R. Decl.”).

2017). Avadel’s disregard of this important policy point should be rejected. Avadel’s reliance on *Purewick*, *ArcherDX*, *Vectura*, and *EMC* should likewise be rejected. Br. at 2-4. Unlike those cases, the change in the parties’ bargaining position here is not limited to the verdict. Avadel admits that, in each cited case, the court found there were no changed post-verdict economic circumstances or other factors unknown to the jury that justified a royalty increase. As discussed below, there are numerous post-verdict factors and evidence unavailable to the jury that support Jazz’s proposed increased rates for Avadel’s ongoing infringement here. *See also* D.I. 687 at 3-7.

II. Post-Verdict Economic Circumstances And Factors The Jury Did Not Consider

Avadel’s proposed royalty is grounded in a flawed and unreliable analysis of the post-verdict *GP* factors. Avadel’s declarant, Dr. Rao, did not even consider the parties’ bargaining positions post-verdict. *See* Rao ¶3; Rainey R. Decl. ¶¶4, 13-15. And neither Avadel nor Dr. Rao considered significant post-verdict economic circumstances and factors unknown to the jury for *GP* factor nos. 3, 5, and 8-10 (Rainey R. Decl. ¶¶4, 17-39) and they also failed to address *GP* factor nos. 1, 4, 11, and 13 (Rainey R. Decl. ¶¶4, 16), which all support Jazz’s proposed rates.

Factors 1 & 4 (royalties received by the patentee; licensing policy): Avadel and Dr. Rao failed to address these factors (Rainey R. Decl. ¶¶4, 16), which support increasing the ongoing royalty. D.I. 687 at 3-4; Rainey Decl. ¶¶17-21, 24-26, 55. Unbeknownst to the jury, Jazz sought an injunction against Avadel’s infringement of claim 24 rather than negotiate a license. D.I. 540 at 7 (precluding evidence relevant to injunction at trial); D.I. 587 at 1; D.I. 687 at 4; *see also Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1315 (Fed. Cir. 2007) (“[T]he district court may wish to allow the parties to negotiate a license amongst themselves.”). Further, in its injunction opinion, the Court did not “disregard” that Jazz has licensed “unrelated patents covering Xyrem and Xywav,” “allowing generic oxybate products to enter the market.” D.I. 665 at 6. These royalties received by Jazz—currently ██████ for the first competitor and ██████ for a competitor that entered the market *after* Avadel—were not considered by the jury but are instructional as to the post-verdict royalty that would adequately compensate Jazz for the continued infringement. Rainey Decl. ¶¶19-20, 24; *id.*, Ex. 1 at §§1.18, 1.39, 1.46, 5.2, 5.2.3; *id.* Ex. 2 at §§1.35, 1.40, 1.41, 5.1; *see also* D.I. 687 at 4; *TC Tech. LLC v. Sprint Corp.*, No. 16-153, 2019 WL 2515779, at *14 (D. Del. June 28, 2019) (“[W]here there is no customary royalty rate ... courts may consider evidence of the parties’ licenses for related technologies to show a range of royalty rates actually paid.”) (citation omitted).

Factor 3 (nature & scope of license): Avadel argues this factor should lower the ongoing royalty because it would reflect a non-exclusive license. Br. at 5. But Dr. Rao’s analysis is flawed, and this factor is neutral or, if anything, favors Jazz. Rainey R. Decl. ¶¶4, 18-25. The license Dr. Rainey discussed at trial was non-exclusive *as to Avadel*; Jazz would retain rights under the ’782 patent. 2/27/24 Rainey Tr. 572:13-23. And although the jury heard that Jazz did not sell a product under the ’782 patent *at the time of trial*, Jazz’s pipeline includes an extended-release product. Rainey R. Decl. ¶19; *id.*, Ex. 33 at 4. There is also a third party developing a low-sodium once-nightly oxybate. Rainey R. Decl., ¶21, Ex. 34. ██████ including a press release from the third party stating that it is applying for Orphan Drug Designation because its product has a lower sodium burden than Lumryz, and ██████. *Id.*; Rainey R. Decl., Ex. 35. Avadel therefore would have incentive to enter into a hypothetical license agreement that is exclusive as to such third parties. Rainey R. Decl. ¶21. Moreover, as Avadel’s proposed order demonstrates, the parties have not requested that the Court craft a non-exclusive license for the ongoing royalty. Br., Avadel Proposed Order.

Factor 5 (relationship of parties as competitors): Avadel and Dr. Rao wrongly argue that there is no change to this factor post-verdict. Br. at 5-6; Rainey R. Decl. ¶¶19, 24, 26-28, 30; D.I. 687 at 5; Rainey Decl. ¶¶10, 27-32, 55, 58-59. At trial, Avadel argued that the parties had an inventor and promoter relationship with respect to Lumryz. *See, e.g.*, 2/27/24 Rainey Tr. 606:18-607:17, 608:16-20. The jury may have credited this argument. But, the Court held post-verdict that “there is no dispute that Lumryz competes directly with Jazz’s oxybate products in the narcolepsy market.” D.I. 665 at 3; *id.* at 31. Avadel has admitted since the verdict that the companies are direct competitors. The parties would understand at the post-verdict negotiation (*GP* factor No. 15) that Jazz would expect to lose ██████████ in sales to Lumryz through expiration of the ’782 patent. Rainey Decl. ¶¶60-67 & Exs. A, A1 (sum of respective Col. [G]). But entering into an ongoing royalty agreement at the jury’s 3.5% rate (or Avadel’s proposed increased 4.2% royalty) would still leave Jazz ██████████ ██████████ D.I. 687 at 5; Rainey Decl. ¶¶73, 57-67, & Exs. C, C1; Rainey R. Decl. ¶¶10, 26-28, 41 & Exs. AA-CC. Given these facts, Jazz has a strong incentive to demand (and could demand) a greater ongoing royalty post-verdict. *See, e.g., Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 670 F.3d 1171, 1193 (Fed. Cir. 2012) (considering that the patentee “lacks incentive to accept a below-market deal”), *vacated on other grounds*, 476 F. App’x 747 (Fed. Cir. 2012); *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, No. 03-597, 2010 WL 11484420, at *3, *6 (D. Ariz. Sept. 9, 2010) (increasing jury’s royalty rate to provide “adequate compensation” and crediting argument that patentee “is more likely to extract a greater royalty from a direct competitor in order to account for lost sales and profits”). Further, the Court denied the narcolepsy injunction primarily because of a public interest finding. D.I. 665 at 8, 12, 21. Given the Court’s finding that the public good should permit Avadel’s continued infringement, the royalty should compensate Jazz as much as possible. *See Bard*, 670 F.3d at 1192 (injunction denied for medical devices on public interest grounds, but royalty enhanced beyond jury award).

Factor 8 (commercial success): Avadel argues, based on Dr. Rao’s flawed analysis (Rainey R. Decl. ¶¶29-34), that this factor should lower the ongoing royalty ██████████ ██████████ Br. at 5-6. This isolated view of the market ignores that numerous post-verdict circumstances and factors not considered by the jury support increasing the royalty. For example, Avadel now believes that the market is not as mature as previously thought and that Lumryz has “unique” opportunities for greater sales; Avadel expects to secure wider insurance coverage, including Medicare/Medicaid in 2025; Avadel increased its wholesale prices and saw a gain in net pricing in Q2 2024; Lumryz’s gross profit margin is over 95%; Lumryz has unexpectedly attracted new prescribers that Avadel did not previously consider; Avadel does not anticipate both new orexin products or generic oxybates to meaningfully hinder growth; Avadel now believes Lumryz is a \$5 billion opportunity, not the \$3 billion opportunity presented to the jury; and Avadel’s market capitalization (a conservative measure of the present value of Avadel’s expected future profits) has grown from \$1.1 billion at trial to over \$1.5 billion. D.I. 687 at 5-6; Rainey Decl. ¶¶34-41, Ex. D; Rainey R. Decl. ¶¶29-34. At the post-verdict hypothetical negotiation, the specter of a permanent injunction would weigh heavily on Avadel given Lumryz’s commercial success and profitability. *Paice III*, 609 F. Supp. 2d at 624 (“[T]he threat of a permanent injunction serves as a big stick.”). Avadel’s ability to sell Lumryz under a license is of paramount importance, and it would pay a higher royalty rate. Rainey Decl. ¶¶40-41.

Factors 9 & 10 (utility, advantages, and benefits): Avadel and Dr. Rao also err by ignoring changed circumstances under these factors to argue that there should be no increase to

the ongoing royalty. Br. at 5; Rainey R. Decl. ¶¶35-39. First, post-verdict evidence shows that (according to Avadel), thirteen months after launch, the claimed dosage form (as embodied by Lumryz) has the added advantage and benefit of lower rates of discontinuation/higher rates of persistency compared to twice-nightly oxybate. D.I. 687 at 6; Rainey Decl. ¶¶45, 55. This metric translates to greater sales of Lumryz over a longer period of time for Avadel. Rainey Decl. ¶¶37, 45. Second, it came to light post-verdict that Avadel’s ’062 patent discloses other dosage forms that Avadel could theoretically develop to design-around claim 24. D.I. 687 at 7. Despite stipulating to infringement and the jury’s affirmation of validity, Avadel has made no effort to do so and admits that it would be an uncertain, time-consuming undertaking. *Id.*; 6/4/24 Hearing Tr. 81:7-82:9. Avadel’s decision to continue its infringement demonstrates that it values the claimed dosage form over these theoretical alternatives, which are technically inferior and/or cost prohibitive. Little Decl. ¶¶11-25; Rainey Decl. ¶¶14, 43, 46-47, 55, 74; Rainey R. Decl. ¶38; *see also Apple, Inc. v. Samsung Elecs. Co.*, No. 12-630, 2014 WL 6687122, at *16-17 (N.D. Cal. Nov. 25, 2014).

Factor No. 11 (extent of use of the invention): Avadel and Dr. Rao did not address this factor. Rainey R. Decl. ¶¶4, 16. But, post-verdict, Lumryz remains Avadel’s only commercial product. On March 11, 2024, Avadel’s CEO explained that, while Avadel is open to acquiring other products as assets in Avadel’s portfolio, such products “would have to ... pass a pretty high bar.” Rainey Decl., Ex. 11 at 20:14-21:17. Because Lumryz remains Avadel’s only commercial product, Avadel would be in a weaker position at the post-verdict hypothetical negotiation.

Factor No. 13 (portion of profit credited to the invention): Avadel and Dr. Rao did not address this factor. Rainey R. Decl. ¶¶4, 16. But, the now-adjudicated inventive contribution of claim 24 to Lumryz also supports a higher ongoing royalty. D.I. 687 at 7; Little Decl. ¶¶11-25; Rainey Decl. ¶¶10, 53, 55; *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1338-40 (Fed. Cir. 2015) (affirming 50% royalty because patent covered whole commercially viable drug). At trial, Avadel argued that claim 24’s inventive contribution was minimal. *See, e.g.*, 2/27/24 Rainey Tr. 605:12-606:17; 3/1/24 Closing Tr. 1217:13-1218:1. Avadel told the jury that “[t]he value of what we got from them [i.e., Jazz] was nothing.” 3/1/24 Closing Tr. 1217:13-16. Avadel complained that Dr. Rainey “didn’t try to figure out the actual value of putting a drug in a sachet or anything that relates to the actual claims of the invention.” *Id.* 1217:20-22. In light of the jury’s 3.5% royalty, the jury likely credited Avadel’s argument. But post-verdict, the Court correctly found that “Avadel intends to offer and sell a wholly infringing product to treat narcolepsy.” D.I. 665 at 31; *see also id.* at 9. The Court also found that the “infringing aspects of Lumryz” should not be treated “‘as a small component part’ of the overall drug.” *Id.* at 9-10. Avadel ignores this major change.

Finally, it is unclear how Avadel determined that the increased royalty “should be on the order of a ten- to twenty- percent increase.” Br. at 1. To the extent that Avadel relies on increases awarded in other cases (*id.* at 3), Avadel disregards the basic principle that damages awards must be tied to the specific facts of the case. *Cf. Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1317-18 (Fed. Cir. 2011) (rejecting 25% rule of thumb because the rule “had no relation to the facts of the case”). And, unlike Jazz and Dr. Rainey, Avadel and Dr. Rao have provided no reliable analysis of the economic factors and bargaining considerations of the parties post-verdict to support Avadel’s proposed de minimis increase.

For the foregoing reasons, and those in Jazz’s opening letter, Jazz’s rates should be ordered.

Respectfully,

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)

JAT/rah

Enclosures

cc: Clerk of the Court (via hand delivery)
All Counsel of Record (via e-mail)