

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	C.A. No. 21-691 (GBW)
	)	
v.	)	PUBLIC VERSION
	)	
AVADEL CNS PHARMACEUTICALS LLC,	)	Confidential Version Filed: September 13, 2024,
	)	Public Version Filed: September 19, 2024
Defendant.	)	

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

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

**PLAINTIFFS' MOTION TO STRIKE DEFENDANT'S REPLY IN SUPPORT OF
ITS EMERGENCY MOTION FOR STAY PENDING APPEAL,
OR IN THE ALTERNATIVE, PLAINTIFFS' SURREPLY THERETO**

I. DEFENDANT’S REPLY SHOULD BE STRICKEN

“The party filing the opening brief shall not reserve material for the reply brief which should have been included in a full and fair opening brief.” D. Del. LR 7.1.3(c)(2). “This provision exists, in part, to prevent litigants from engaging in impermissible ‘sandbagging,’ reserving crucial arguments for a reply brief to which an opponent cannot respond.” *Fifth Mkt., Inc. v. CME Grp.*, No. 08-520, 2013 WL 3063461, at *1 n.2 (D. Del. June 19, 2013). “Arguments raised for the first time before a district court in a reply brief are deemed forfeited.” *Int’l Constr. Prods. v. Caterpillar Inc.*, No. 15-108, 2024 WL 406433, at *2 (D. Del. Feb. 2, 2024).

Jazz noted this in Opposition (D.I. 679, “Opp.” at 10) because it foresaw that Avadel would for the first time in Reply raise arguments ***on which Avadel bears the burden and Jazz noted Avadel failed to address***. Avadel did just that. For the first time, Avadel asserts: (1) its infringement falls under §271(e)(1)’s “patented invention”; (2) the Court should credit Avadel’s §271(e)(1) “reasonably related” argument without any factual record; and (3) it preserved the safe harbor affirmative defense. The Court should either strike Avadel’s brief or, in the alternative, consider Jazz’s short sur-reply below. *See Waters Techs. Corp. v. Aurora SFC Sys. Inc.*, No. 11-708, 2012 WL 13167829, at *1 (D. Del. Apr. 20, 2012) (Judge Andrews noting “I have previously granted requests [to sur-reply to new arguments raised in Reply] . . . I think the better way to handle this situation is to consider motions to strike portions of reply brief. . . .”).

II. ALTERNATIVELY, THE COURT SHOULD CONSIDER JAZZ’S SURREPLY

Each of Avadel’s new arguments raised for the first time in Reply lacks merit.

Avadel’s New “Patented Invention” Argument Fails – Avadel argues that this case should be treated differently than *Proveris* and its lineage because Judge Robinson purportedly rejected “a similar argument” in *Wesley Jessen*. D.I. 684 (“Reply”) at 4-5. But *Wesley Jessen* does not

address the “patented invention” inquiry. Rather, *Wesley Jessen* was decided in 2002 before the Federal Circuit analyzed the “patented invention” inquiry in *Proveris* in 2008. Consequently, when Judge Robinson made her decision, she noted the absence of case law and that the decision was based on “guiding principles from the Federal Circuit” at that time. 235 F.Supp.2d 370, 374 (D. Del. 2002). Since 2002, the Federal Circuit has set “guiding principles” for the interpretation of the “patented invention” inquiry of § 271(e)(1) (*Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265-66 (Fed. Cir. 2008)), and this District follows them. *See Regenxbio Inc. v. Sarepta Therapeutics, Inc.*, No. 20-1226, 2022 WL 609141, at *3 (D. Del. Jan. 4, 2022) (“Following *Proveris*, several district courts have held that where the patented product is not subject to FDA premarket approval, the safe harbor does not apply.”).

Avadel Cannot Prove The “Reasonably Related” Prong With No Evidence – Avadel argues that it needs no evidence on the “reasonably related” prong based on a factually unsupported statement that “Avadel’s IH study is a precursor to FDA submission” and that “courts routinely find FDA-approved studies like Avadel’s per se protected.” Reply at 5. But Avadel’s arguments that it need not prove that its studies are required for FDA approval fails because, as the Federal Circuit recently explained in *Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd.*, “***each act*** of infringement” must be “reasonabl[y] relat[ed] to the development and submission of information to the FDA.” 96 F.4th 1347, 1353 (Fed. Cir. 2024) (emphasis added). Thus, as Jazz noted in Opposition, Avadel bore the burden of demonstrating that “***each use*** of the infringing Lumryz dosage form ***in each clinical trial*** is required to obtain or maintain FDA approval of an IH indication.” Opp. at 10-11. Avadel never presented any evidence on whether any studies are necessary and, if so, the number of patients needed or whether any open-label extension is needed. As such, it cannot win on these issues on appeal.

Avadel also misstates (and ignores) the law from *Edwards* that Jazz raised. Avadel argues it need not show that the “sole purpose of its IH clinical study is FDA approval,” (Reply at 6), but ignores that it must show that “the ‘sole purpose’ . . . is *not* ‘to support its commercial sales efforts.’” Opp. at 12 (quoting *Edwards*). Avadel failed to present that evidence and concedes, by not addressing, that it is undertaking all the commercial activities noted by Jazz. See Opp. at 2-3, 12-13, 17-18. Indeed, their commercial nature cannot be seriously disputed.

And as Jazz explained, factual evidence is critical here. Indeed, each of Avadel’s cited cases was decided based on robust factual records, which makes them very different from the case here. See *Nexell Therapeutics, Inc. v. AmCell Corp.*, 199 F. Supp. 2d 197, 203-05 (D. Del. 2002) (“Based on the facts before the court, the court determined that AmCell’s activities were ‘reasonably related’ to obtaining FDA approval. . . .”); *Intermedics, Inc. v. Ventritex Co.*, 991 F.2d 808, at *3 (Fed. Cir. 1993) (Federal Circuit relying on trial court’s factual finding “that Ventritex did not sell a single Cadence as a result of the demonstrations”).

The Burden Was On Avadel To Raise A Safe Harbor Defense – Lastly, Avadel attempts to blame everyone but itself, including this Court and Jazz, for Avadel’s failure to raise the safe harbor affirmative defense. Avadel’s attempt fails.

First, Avadel incorrectly argues that Jazz’s Complaint supposedly carves out safe harbor activities, and that this Court’s injunction goes too far by enjoining future acts. On the first point, Avadel ignores that its activities are not protected by the safe harbor and then cites only one paragraph of the Complaint in isolation and omits the rest. See Reply at 7 (citing C.A. No. 21-1594, D.I. 211 (“Cmplt.”) at ¶ 34). Jazz’s Complaint clearly seeks relief – Jazz alleges that all of “Avadel’s making, using, selling, offering to sell, and/or importing Avadel’s Proposed Product will infringe one or more claims of the patent-in-suit” and expressly seeks “[a] permanent

injunction enjoining” all of those infringing activities. Cmpl’t. at Prayer for Relief ¶¶ A-B. And Avadel does not dispute Jazz’s argument (Opp. at 6) that the infringement stipulation Avadel agreed to for claim 24 (D.I. 550) does not carve out any of Avadel’s IH activities. A “district court err[s] by failing to enforce the parties’ stipulation” regarding infringement. *Ring & Pinion Service Inc. v. ARB Corp.*, 743 F.3d 831, 836 (Fed. Cir. 2014). “A stipulation of fact that is fairly entered into is controlling on the parties and the court is generally bound to enforce it.” *Id.* Finally, Avadel ignores that “injunctions are tools for prospective relief designed to alleviate future harm” and are, therefore, squarely directed at future acts. *See i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010), *aff’d*, 564 U.S. 91 (2011).

Second, Avadel wrongly argues Jazz conceded Avadel’s studies are protected by the safe harbor at the injunction hearing. But Jazz actually said (on an issue never raised or briefed before): “I don’t think that’s accurate. . . I don’t think they get a safe harbor provision.” Reply, Ex. D at 100-101.

Third, Avadel incorrectly argues that Jazz stated it was not seeking to enjoin the IH Trial. Not so. Jazz’s requested injunction—filed on April 12, 2024—carved out “**currently on-going**” trials at that time. At the time of the materials Avadel cites—the June 4 hearing and Jazz’s June 13 letter (Reply at 1, 6-7)—it is undisputed that Avadel had not initiated the IH Trial. It is also undisputed that Avadel affirmatively told the Court it would not do that trial if enjoined. Further, Jazz has always been clear: It is not seeking to stop Avadel, *in vacuum*, from selling any once-nightly dosage form, applying for FDA approval for IH, or conducting an IH trial. *See* D.I. 610 at 1; Opp. at 13; D.I. 650 at 1. Instead, Jazz is seeking to stop Avadel’s use of the infringing dosage form of claim 24 in those activities. Avadel’s attempt to spin things otherwise fails.

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RULE 7.1.1 CERTIFICATE

I hereby certify that Plaintiffs reached out to counsel for Defendant to seek its position on this motion and, although Plaintiffs have not received confirmation, anticipates that Defendant will oppose.

/s/ Jeremy A. Tigan

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CERTIFICATE OF SERVICE

I hereby certify that on September 13, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 13, 2024, upon the following in the manner indicated:

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