

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-691 (MN)
	)	
AVADEL CNS PHARMACEUTICALS LLC,	)	
	)	
Defendant.	)	

**JAZZ’S MOTION FOR LEAVE TO FILE SUR-REPLY**

Plaintiff Jazz Pharmaceuticals, Inc. respectfully moves for leave to file the attached sur-reply (Ex. A) in response to Defendant Avadel CNS Pharmaceuticals LLC’s Renewed Motion for Partial Judgment on the Pleadings and states as follows:

Local Rule 7.1.3.(c)(2) states that “[t]he 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.” See also *Laborers’ Int’l Union of North Am. v. Foster Wheeler Corp.*, 26 F.3d 375, 398 (3rd Cir. 1994) (holding an issue is waived unless a party raises it in its opening brief and “passing reference” to an issue will not suffice); *Rockwell Techs., LLC. v. Spectra-Physics Lasers, Inc.*, No. 00-589-GMS, 2002 WL 531555, at \*3 (D. Del. Mar. 26, 2002) (finding the “tactic of reserving new arguments for its reply brief amounts to impermissible ‘sandbagging.’”); *EIS, Inc. v. WOW Tech Int’l GmbH*, No. 19-1227-LPS, 2020 WL 7027528, at \*7 (D. Del. Nov. 30, 2020) (“Because these new arguments and new authority were presented for the first time on reply, Defendants’ positions are untimely and are deemed waived.”). A new argument in reply should be disregarded for this reason alone. *Barna v. Bd. of Sch. Directors of Panther Valley Sch. Dist.*, 877 F.3d 136, 146 (3d Cir. 2017) (declining to “reach arguments raised for the first time in a reply brief.”); accord *Banner v. Fletcher*, 834 F. App’x 766, 769 (3d Cir. 2020).

Nevertheless, a Court may grant leave to file a sur-reply if it responds to new evidence, facts, or arguments.” *See St. Clair Intellectual Prop. Consultants, Inc. v. Samsung Elecs. Co., Ltd.*, 291 F.R.D. 75, 80 (D. Del. 2013) (granting motion to file sur-reply where it would “allow the Court to more fully and fairly evaluate Defendants’ pending motion to dismiss” by “explain[ing] Plaintiff’s view of the newly presented evidence”). A party should have a full and fair opportunity to brief the issues before they are resolved. *See Massey v. Del Labs., Inc.*, 118 F.3d 1568, 1572-73 (Fed. Cir. 1997); *see also Alston v. Forsyth*, 379 Fed. App’x 126, 129 (3d Cir. 2010) (“Fundamental fairness demands that [Appellant] should have had notice and a meaningful opportunity to respond prior to the award of summary judgment on grounds raised for the first time in Appellee’s reply brief.”).

Jazz seeks leave to file a four-page sur-reply in opposition to Avadel’s motion. A sur-reply is warranted because in the opening brief in support of its motion (as well as in its original Rule 12(c) briefing), Avadel rooted its delisting arguments under its proposed claim construction on whether Jazz properly listed the ’963 patent under 21 U.S.C. § 355(b)(1)(A)(viii)(I-II), § 355(c)(2), and 21 C.F.R. § 314.53(b). *See* D.I. 21 at 2, D.I. 47 at 6, D.I. 118 at 6-9. Avadel relied on 21 U.S.C. § 355(j)(5)(C)(ii)(I) and 21 U.S.C. § 355(c)(3)(D)(ii)(I) for “remedy” purposes only. *See* D.I. 118 at 5, 11. Consequently, in its opposition brief Jazz explained why the former cited provisions did not provide for delisting and, thus, why Avadel’s proposed remedy should not be granted. *See* D.I. 153. In reply, however, Avadel changed the statutory foundation of its request by using the language of 21 U.S.C. § 355(j)(5)(C)(ii)(I) and § 355(c)(3)(D)(ii)(I) to argue that delisting must be granted if Avadel’s proposed “computer systems” construction is adopted. *See, e.g.*, D.I. 154 at 1. Avadel’s new argument is improperly raised in reply and Jazz has not had a fair opportunity to respond. Moreover, Jazz respectfully

submits that Avadel's new position is based on a misapplication of the law and the Court would benefit from Jazz's brief explanation of the relevant statutes and authority.

Accordingly, Jazz respectfully requests leave to file its proposed sur-reply. A proposed form of order is attached.

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*/s/ Jeremy A. Tigan*

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August 30, 2022

**RULE 7.1.1 CERTIFICATE**

I hereby certify that Delaware counsel for the parties discussed the subject of the foregoing motion and were unable to reach agreement. The parties met and conferred via phone and email yesterday and Jazz provided Avadel with the specific basis for its sur-reply both orally and via email. Avadel requested that Jazz provide it with an advance copy of the proposed sur-reply, stating that it would oppose at least on that basis if not provided, and also stated that Avadel disagreed it had changed the basis for its requested relief.

*/s/ Jeremy A. Tigan*

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Jeremy A. Tigan (#5239)



**CERTIFICATE OF SERVICE**

I hereby certify that on August 30, 2022, 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 August 30, 2022, upon the following in the manner indicated:

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