

**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

**UNSEALED ON 12/13/22**

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**MEMORANDUM ORDER**

Before the Court is Plaintiff Jazz Pharmaceuticals, Inc.'s ("Jazz") Motion to Stay Pending Appeal or, in the Alternative, a Stay Pending Application to the Federal Circuit for a Stay Pending Appeal (the "Motion to Stay"). D.I. 236. The Motion has been fully briefed. D.I. 236, 244, 253. For the following reasons, the Motion to Stay is denied.

**I. BACKGROUND**

On November 18, 2022, this Court issued a Memorandum Opinion (the "Delisting Opinion") granting Defendant Avadel CNS Pharmaceuticals LLC's ("Avadel") renewed motion for judgment on the pleadings with respect to its counterclaim seeking delisting of Plaintiff Jazz Pharmaceuticals, Inc.'s ("Jazz") U.S. Patent No. 8,731,963 ("the '963 patent") from the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book"). D.I. 231. As a result, this Court ordered Jazz to request that the FDA delete the '963

patent from the Orange Book entry for Xyrem®<sup>1</sup> by December 2, 2022 (the “Delisting Order”). D.I. 232.

On November 22, 2022, Jazz appealed the Delisting Order, D.I. 234, and filed the instant Motion to Stay, D.I. 235, arguing that this Court should stay its Delisting Order or “grant a one-month stay while Jazz petitions the Federal Circuit to stay the injunction pending appeal.” D.I. 236. On November 29, 2022, the Federal Circuit “temporarily stayed” the Delisting Order “until further notice of this court” and “held in abeyance” Jazz’s motion to stay filed in its appeal. D.I. 250 at 2. The Federal Circuit further ordered that, “The parties should promptly inform this court when the district court resolves the motion for a stay pending before that court.” *Id.*

## II. LEGAL STANDARD

In deciding whether to grant a motion to stay final judgment, courts consider four factors: “(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.” *Standard Havens Prod., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990) (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)). The application of those factors lies within the court’s discretion. *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, C.A. No. 18-1043 (KAJ), 2020 WL 8187586, at \*2 (D. Del. Dec. 10, 2020).

## III. DISCUSSION

As to the first factor (“whether the stay applicant has made a strong showing that he is likely to succeed on the merits”), Jazz first contends that it is “likely to prevail on novel questions

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<sup>1</sup> Jazz manufactures and sells a Xyrem®, an FDA-approved drug for treating cataplexy and excessive daytime sleepiness associated with the sleep disorder narcolepsy.

of statutory construction regarding the applicability of the statutory counterclaim in 21 U.S.C. § 355(c)(3)(D)(ii)(I)” because the Orange Book Transparency Act does not apply retroactively and Jazz was permitted to list the ’963 patent in the Orange Book. D.I. 236 at 1-2. This Court has already considered and rejected Jazz’s arguments. D.I. 231 at 6-7. Second, Jazz argues that the ’963 patent is “appropriately listed in the Orange Book even if construed as a system patent” because “[t]here is no evidence that Congress meant the word ‘method’ to import patent-law concepts” into the meaning of “an approved method of using the drug” as that phrase appears in 21 U.S.C. § 355(c)(3)(D)(ii)(I)(bb). D.I. 236 at 8-15. However, Jazz did not previously raise this argument before this Court. Thus, it has been forfeited. *See In re Google Tech. Holdings LLC*, 980 F.3d 858, 862–63 (Fed. Cir. 2020) (“a position not presented in the tribunal under review will not be considered on appeal in the absence of exceptional circumstances”). Accordingly, Jazz has not made a strong showing that it is likely to succeed on the merits.

As to the remaining factors (“whether the applicant will be irreparably injured absent a stay”, “whether issuance of the stay will substantially injure the other parties interested in the proceeding”, and “where the public interest lies”), Jazz argues that, if it is required to delist the ’963 patent, “the pediatric exclusivity will likely evaporate when the patent expires on December 17, 2022,” D.I. 236 at 15, and that “Avadel will not suffer any harm as a result of the stay because Avadel’s product, FT218, cannot be lawfully marketed even if Jazz delists the ’963 patent” because the FDA has not determined whether certain Orphan Drug Exclusivity protections preclude approval of Avadel’s NDA, *id.* at 16. Jazz’s use of conditional language (that its exclusivity will “likely” evaporate) seems to reveal that, at a minimum, the timing of any ensuing harm to Jazz is uncertain—a fact made plain in light of Jazz’s own assertions that Avadel’s product cannot be marketed immediately. While Jazz complains that delisting will result in the “irrevocable” loss

of its “patent rights,” D.I. 236 at 17, Congress contemplated this kind of situation when it created a unique right of action under which an NDA applicant may “assert a counterclaim seeking an order requiring the [patentholder] to correct or delete” an Orange Book listing blocking the FDA’s approval of its application. 21 U.S.C. § 355(c)(3)(D)(ii)(I). This Court would be “undermin[ing] congressional intent and the public interest” were it to grant Jazz’s motion. *Novartis*, 2020 WL 8187586, at \*2. Also, injury would befall Avadel if this Court were to stay implementation of the Delisting Order, effectively withholding the very remedy to which Avadel is statutorily and expeditiously entitled.<sup>2</sup> Thus, Jazz has not demonstrated that the remaining factors favor a stay.<sup>3</sup>

#### IV. CONCLUSION

For the foregoing reasons, the Motion to Stay is denied.

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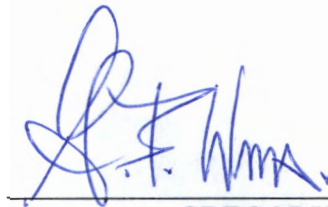
<sup>2</sup> Indeed, recognizing the importance of timing to this issue, the Court granted Avadel’s Motion to Expedite Consideration of its Renewed Motion for Partial Judgment on the Pleadings (D.I. 162). D.I. 212.

<sup>3</sup> Because the Court has determined that a stay is not warranted, the Court need not evaluate whether a bond is appropriate pursuant to Fed. R. Civ. P. 62(d). *See* D.I. 244 & 253.



**WHEREFORE**, this 5<sup>th</sup> day of December, 2022, **IT IS HEREBY ORDERED** that:

1. Plaintiff Jazz Pharmaceuticals, Inc.'s ("Jazz") Motion to Stay Pending Appeal or, in the Alternative, a Stay Pending Application to the Federal Circuit for a Stay Pending Appeal (D.I. 236) is **DENIED**.
2. Because the Memorandum Order is filed under seal, the parties shall meet and confer and, no later than December 12, 2022, submit a joint proposed public redacted version. In the absence of a timely request compliant with applicable standards, the Court will unseal the entire Order.



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GREGORY B. WILLIAMS  
UNITED STATES DISTRICT JUDGE