IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff / Counter-Defendant, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant / Counter-Plaintiff.	Civil Action No. 22-941-GBW

Jeremy A. Tigan, Cameron P. Clark, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE; F. Dominic Cerrito, Steig D. Olson, Gabriel P. Brier, Frank C. Calvosa, Nicolas Siebert, Maxwell Hawley, Kevin Adams, John P. Galanek, Habib-Emmanuel Abraham, Sami H. Rashid, Elizabeth J. Murphy, QUINN EMANUEL URQUHART & SULLIVAN, LLP, New York, NY; William R. Sears, Lynette Lim, QUINN EMANUEL URQUHART & SULLIVAN, LLP, Los Angeles, CA.

Counsel for Plaintiff / Counterclaim Defendant

Daniel M. Silver, Alexandra M. Joyce, MCCARTER & ENGLISH, LLP, Wilmington, DE; Kenneth G. Schuler, Marc N. Zubick, Alex Grabowski, Sarah W. Wang, LATHAM & WATKINS LLP, Chicago, IL; Ian R. Conner, Alan J. Devlin, Anna Rathbun, Christopher J. Brown, LATHAM & WATKINS LLP, Washington, D.C.; Herman Yue, LATHAM & WATKINS LLP, New York, NY; Alfred C. Pfeiffer, LATHAM & WATKINS LLP, San Francisco, CA; Daralyn J. Durie, Rebecca E. Weires, Tannyr Pasvantis, Eliot A. Adelson, Margaret A. Webb, Helen He, MORRISON & FOERSTER LLP, San Francisco, CA; Kira A. Davis, Henry Huttinger, Katherine E. McNutt, MORRISON & FOERSTER LLP, Los Angeles, CA; Alexander Okuliar, Haydn Forrest; MORRISON & FOERSTER LLP, Washington, D.C.; Matthew C. Has, POLSINELLI, St. Louis, MO.

Counsel for Defendant / Counterclaim Plaintiff

MEMORANDUM OPINION

September 15, 2025
Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Pending before the Court are Jazz's[1] Motion for Summary Judgment No. 1: No Antitrust Standing ("Jazz's MSJ No. 1") (D.I. 245) and Jazz's Motion for Summary Judgment No. 2: No Antitrust Liability ("Jazz's MSJ No. 2) (D.I. 246), both of which have been fully briefed (D.I. 247; D.I. 293; D.I. 313). For the reasons discussed below, the Court denies both motions.

I. BACKGROUND

On July 15, 2022, Jazz filed a Complaint for Patent Infringement ("Complaint") in this Court alleging that Avadel infringes U.S. Patent No. 8,731,963 (the "'963 patent"). D.I. 1. ¶ 1. On October 21, 2022, Avadel filed an Answer to Complaint for Patent Infringement, Defenses, and Counterclaims ("Counterclaim"). D.I. 14.[2]

In its Counterclaim, Avadel alleged that Jazz violated Section 2 of the Sherman Act by listing and refusing "to delist the '963 patent—a REMS[3] patent that claims a distribution system—in the Orange Book." D.I. 14 ¶ 136. Avadel alleged that "Jazz did this, even though the owner of an FDA-approved drug product may only list in the Orange Book patents that claim the active pharmaceutical ingredient, composition or formulation, or method of using that drug." D.I. 14 ¶ 136. Avadel further alleged that the improper listing of the '963 patent and maintenance

[1] The Plaintiff and Counterclaim Defendant is Jazz Pharmaceuticals, Inc. ("Plaintiff" or "Counterclaim Defendant" or "Jazz"). The Defendant and Counterclaim Plaintiff is Avadel CNS Pharmaceuticals LLC ("Defendant" or "Counterclaim Plaintiff" or "Avadel").

[2] On March 7, 2023, this Court ordered the dismissal, per stipulation, of Jazz's claim for infringement and Avadel's corresponding counterclaims of non-infringement / invalidity / de-listing of the '963 patent. *See* D.I. 32. Thus, only Avadel's antitrust counterclaims remained (and remain).

[3] REMS means Risk Evaluation and Mitigation Strategy. *See* D.I. 247 at 6.

thereof was an attempt "to impede any pharmaceutical company that may try to launch a competitive oxybate[4] product." D.I. 14 ¶ 137. In particular, Avadel alleged that the improper listing and maintenance thereof caused the FDA to decide "that it could not approve Avadel's NDA[5] unless Avadel filed a Paragraph IV certification." D.I. 14 ¶ 137. "That certification, in turn," according to Avadel, "allowed Jazz to file this lawsuit, further delaying the FDA's ability to grant final approval to LUMRYZ by triggering an automatic stay." D.I. 14 ¶ 137.

On November 18, 2022, in a separate but related action between the parties, this Court ordered Jazz to "submit to the FDA a request enclosing this Order to delete the '963 patent from the Orange Book" since "the '963 patent [did] not claim either 'the drug for which the application was approved' or 'an approved method of using the drug' consistent with 21 U.S.C. § 355(c)(3)(D)(ii)(I)." No. 21-691, D.I. 232 at 1-2.

On December 9, 2022, Jazz filed a Motion to Dismiss Avadel's Antitrust Counterclaims ("Motion to Dismiss"). D.I. 21. On June 29, 2023, Jazz filed a Motion for Leave to File Its Supplemental Brief in Support of Its Motion to Dismiss ("Motion to Supplement"). D.I. 48. In the attached proposed supplemental brief, Jazz contended that the FDA had "publicly released judicially noticeable documents that disprove . . . that Jazz's listing of the '963 patent in the Orange Book delayed the launch of LUMRYZ" and that, accordingly, Avadel could not "plausibly allege antitrust standing" with respect to its antitrust counterclaims. D.I. 48-1 at 1.

On May 24, 2024, the Court denied Jazz's Motion to Supplement. D.I. 94. The Court explained: "Viewing the facts in the light most favorable to Avadel, Avadel has plead facts

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[4] Oxybate is used to treat narcolepsy. *See* D.I. 247 at 4-5.

[5] Avadel's NDA (New Drug Application) sought approval for LUMRYZ, Avadel's oxybate product. *See* D.I. 247 at 7.

sufficient to show that the FDA would have granted Avadel's NDA for LUMRYZ prior to Jazz's delisting of the '963 patent," i.e., that Avadel plead facts sufficient to show antitrust standing. D.I. 94 at 16. Those sufficiently alleged facts included that (1) "the FDA concluded that LUMRYZ was clinically superior to XYREM[6] only eight weeks after Jazz delisted the '963 patent[7]" and (2) the FDA "had no reason to determine whether LUMRYZ was clinically superior to XYREM while the '963 patent remained listed in the Orange Book because the FDA's general practice is not to make a determination regarding the impact of ODE[8] on the approvability of an application until the FDA is otherwise ready to take an approval action on such [an] application." D.I. 94 at 16 (cleaned up).

On April 25, 2025, Jazz filed its MSJ No. 1. D.I. 245. In its opening brief in support of its MSJ No. 1, Jazz contends that "Avadel lacks antitrust standing because it cannot show the FDA would have approved LUMRYZ by October 15, 2021" but for Jazz's improper listing and maintenance of the '963 patent in the Orange Book. D.I. 247 at 16. This contention is essentially the same issue previously presented by Jazz's Motion to Supplement, but now in the vehicle of a motion for summary judgment.

II. LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R.

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[6] XYREM is Jazz's oxybate product. *See* D.I. 247 at 5-6.

[7] Superiority was necessary for FDA approval. *See* D.I. 247 at 8.

[8] ODE means orphan drug exclusivity. *See* D.I. 247 at 5. ODE status supports "the development and evaluation of new treatments for rare diseases." Designating an Orphan Product: Drugs and Biological Products, FDA (last viewed Sept. 8, 2025), https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products.

Civ. P. 56(a). "A genuine issue of material fact is one that could lead a reasonable jury to find in favor of the nonmoving party." *Bletz v. Corrie*, 974 F.3d 306, 308 (3d Cir. 2020). "The court must review the record as a whole, draw all reasonable inferences in favor of the nonmoving party, and must not 'weigh the evidence or make credibility determinations.'" *Id.* at 308 (quoting *Parkell v. Danberg*, 833 F.3d 313, 323 (3d Cir. 2016)).

III. DISCUSSION

As described above, Jazz contends in its MSJ No. 1 that "Avadel lacks antitrust standing because it cannot show the FDA would have approved LUMRYZ by October 15, 2021" but for Jazz's improper listing and maintenance of the '963 patent in the Orange Book. D.I. 247 at 16. Antitrust standing is distinct from constitutional standing and is determined using the following multifactor test:

> (1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages.

SEI Glob. Servs. v. SS&C Advent, No. 20-3386, 2022 U.S. App. LEXIS 18121, at *5-6 (3d Cir. June 30, 2022) (quoting *Ethypharm S.A. France v. Abbott Lab'ys*, 707 F.3d 223, 232-33 (3d Cir. 2013)). The "presence of the requisite causation," i.e., the issue raised by Jazz's MSJ No. 1, "is normally a question of fact for a jury." *See Roxane Labs., Inc. v. Smithkline Beecham Corp. (In re Flonase Antitrust Litig.)*, 798 F. Supp. 2d 619, 627 (E.D. Pa. 2011) (cleaned up) (regarding motion for summary judgment on causation grounds in an antitrust litigation).

Here, there is a genuine dispute of material fact regarding when the FDA would have approved Avadel's NDA for LUMRYZ but for Jazz's listing of the '963 patent in the Orange

Book. Specifically, at least two facts / arguments from Avadel show that this ultimate question is genuinely disputed: (1) that "the FDA concluded that LUMRYZ was clinically superior to XYREM only eight weeks after Jazz delisted the '963 patent" and (2) that the FDA, at least arguably, "had no reason to determine whether LUMRYZ was clinically superior to XYREM while the '963 patent remained listed in the Orange Book." D.I. 94 at 16 (cleaned up); *cf.* D.I. 313 at 4-6 (disputing the import of these two facts / arguments). In light of this genuine dispute of material fact, the Court denies Jazz's MSJ No. 1.[9] Since the Court denies Jazz's MSJ No. 1, the Court denies Jazz's MSJ No. 2 pursuant to the Court's summary judgment ranking procedures.

IV. CONCLUSION

For all of the foregoing reasons, the Court denies Jazz's Motion for Summary Judgment No. 1: No Antitrust Standing (D.I. 245) and Jazz's Motion for Summary Judgment No. 2: No Antitrust Liability (D.I. 246). The Court will enter an Order consistent with this Memorandum Opinion.

[9] "[Jazz's] [MSJ No. 1] is actually two motions for summary judgment and, thus, the Court only considers the first issue presented in [Jazz's] [MSJ No. 1] and denies the second issue pursuant to the Court's summary judgment ranking procedures." *See Nexus Pharms., Inc. v. Exela Pharma Scis., LLC*, Civil Action No. 22-1233-GBW, 2025 LX 215697, at *5 n.3 (D. Del. July 7, 2025).

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ORDER

At Wilmington this 15th day of September 2025, **IT IS HEREBY ORDERED** that Jazz's Motion for Summary Judgment No. 1: No Antitrust Standing (D.I. 245) and Jazz's Motion for Summary Judgment No. 2: No Antitrust Liability (D.I. 246) are **DENIED**.

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE